

TUCKER ELLIS & WEST LLP
MICHAEL C. ZELLERS-STATE BAR NO. 146904
MOLLIE BENEDICT-STATE BAR NO. 187084
AGGIE B. LEE-STATE BAR NO. 228332
515 S. Flower Street, 42nd Floor
Los Angeles, CA 90071-2223
Telephone: (213) 430-3400
Facsimile: (213) 430-3409
michael.zellers@tuckerellis.com
mollie.benedict@tuckerellis.com
aggie.lee@tuckerellis.com

Attorneys for Defendant
BRACCO DIAGNOSTICS INC.

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA**

CAROL MOORHOUSE and JAMES
MOORHOUSE,

Plaintiffs,

v.

BAYER HEALTHCARE
PHARMACEUTICALS, INC.; BAYER
HEALTHCARE LLC; GENERAL
ELECTRIC COMPANY; GE
HEALTHCARE, INC.; COVIDIEN,
INC.; MALLINCKRODT, INC.;
BRACCO DIAGNOSTICS, INC.;
McKESSON CORPORATION;
MERRY X-RAY CHEMICAL CORP.;
and DOES 1 through 35,

Defendants.

Case No. CV-08-1831 SBA

**DEFENDANT BRACCO
DIAGNOSTICS INC.'S
OPPOSITION TO PLAINTIFFS'
MOTION TO REMAND**

[Filed Concurrently with Declaration of
Aggie B. Lee and Proposed Order]

Date: June 10, 2008
Time: 1:00 p.m.
Courtroom: 3

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

Defendant Bracco Diagnostics Inc. ("BDI") hereby submits its Opposition to
Plaintiffs' Motion to Remand.

TABLE OF CONTENTS

	<u>PAGE</u>
I. SUMMARY OF ARGUMENT	1
II. FACTS AND PROCEDURAL BACKGROUND	2
III. PLAINTIFFS' CLAIMS FAIL TO STATE ANY LEGALLY PLAUSIBLE CLAIM(S)	3
IV. ARGUMENT	4
A. THE FRAUDULENT JOINDER STANDARD UNDER THE RECENT SUPREME COURT DECISION IN <i>BELL ATLANTIC V. TWOMBLY</i>	4
B. PLAINTIFFS FAIL TO ALLEGE ANY PLAUSIBLE CLAIM AGAINST THE DISTRIBUTOR DEFENDANTS	6
1. PLAINTIFFS' TORT CLAIMS AGAINST THE DISTRIBUTOR DEFENDANTS FAIL AS A MATTER OF LAW	7
2. PLAINTIFFS FAIL TO STATE A VIABLE CLRA CLAIM AGAINST THE DISTRIBUTOR DEFENDANTS	8
a) Gadolinium-Based Contrast Agents are Not in the Class of Products Covered by the CLRA	8
b) Plaintiffs' CLRA Claims Against the Distributor Defendants are Legally Insufficient	8
c) Plaintiffs Failed to Adhere to the Notice Requirements of the CLRA	10
C. IN THE ALTERNATIVE, THIS COURT SHOULD STAY THIS MATTER AND DEFER RULING ON THE REMAND MOTION	10

V. CONCLUSION..... 11

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

TABLE OF AUTHORITIES**PAGE****CASES**

<i>Aronis v. Merck & Co.</i> , 2005 U.S. Dist. LEXIS 41531 (E.D. Cal 2005)	6
<i>Beatty v. Merck & Co.</i> , 2006 U.S. Dist. LEXIS 77260 (E.D. Cal. 2006)	11
<i>Bell Atlantic Corp. v. Twombly</i> , -- U.S. ---, 127 S.Ct. 1955, 1965, 1974 (2007)	passim
<i>Cattie v. Wal-mart Stores, Inc.</i> , 504 F. Supp. 2d 939 (S.D. Cal 2007)	8, 10
<i>Choyce v. Saylor</i> , 2007 WL 3035406, at *2 (N.D. Cal. Oct. 16, 2007)	6, 9
<i>Cline v. Merck & Co.</i> , 2006 U.S. Dist. LEXIS 34417 (E.D. Cal. 2006)	11
<i>Conley v. Gibson</i> , 355 U.S. 41 (1957)	5
<i>Conroy v. Fresh Del Monte Produce, Inc.</i> , 325 F. Supp. 2d 1049 (N.D. Cal. 2004)	2, 11
<i>English v. Merck & Co.</i> , 2007 U.S. Dist. LEXIS 14493 (E.D. Cal. 2007)	11
<i>Farm Raised Salmon Cases</i> , 42 Cal.4th 1077 (2008)	8
<i>Harara v. Landamerica Financial Group Inc.</i> , No. C 07-03999 WHA, 2007 WL 2938172 at 4 (N.D. Cal. Oct. 9, 2007)	5
<i>Hardin v. Merck & Co., Inc.</i> , 2007 WL 1056790 (N.D. Cal. 2007)	11
<i>Int'l Norcent Tech. v. Koninklijke Philips Elect. N.V.</i> , No. CV07-00043MMM (SSx), 2007 WL 4976364, (C.D. Cal. Oct. 29, 2007)	2, 9
<i>Johnson v. Merck & Co.</i> , 2005 U.S. Dist. LEXIS 40703 (N.D. Cal. 2005)	11
<i>Johnson v. Merck & Company</i> , No. C 07-00067 WHA, 2007 WL 754882 (N.D. Cal. Mar. 8, 2007)	2

1	<i>Laster v. T-Mobile USA Inc.</i> ,	
2	407 F. Supp. 2d 1181 (S.D. Cal. 2005)	8, 10
3	<i>Leeson v. Merck & Company</i> ,	
4	NO. S-05-2240 WBS PAN, 2006 WL 3230047 *1 (E.D. Cal. Jan. 27, 2006) .	2, 7,
5	10, 11	
6	<i>North Star Int'l v. Arizona Corp. Comm'n</i> ,	
7	720 F.2d 578 (9th Cir. 1983).....	5
8	<i>Oestreicher v. Alienware Corp.</i> ,	
9	---F. Supp. ---, No. C 07-00512 MHP, 2008 WL 906550 (N.D. Cal. Apr. 1,	
10	2008).....	1
11	<i>Outboard Marine Corp. v. Superior Court</i> ,	
12	52 Cal.App.3d 30 (1975).....	8, 10
13	<i>Parks Sch. of Bus. v. Symington</i> ,	
14	51 F.3d 1480 (9th Cir. 1995).....	6
15	<i>Purcell v. Merck & Co.</i> ,	
16	2005 U.S. Dist. LEXIS 41239 (S.D. Cal. 2005)	11
17	<i>Roe III v. Unocal Corp.</i> ,	
18	70 F. Supp. 2d 1073 (C.D. Cal. 1999).....	5
19	<i>Smith v. Mail Boxes, Etc.</i> ,	
20	191 F. Supp. 2d 1155 (E.D. Cal. 2002).....	11
21	<i>TPS Utilicom Services, Inc.</i> ,	
22	223 F. Supp. 2d 1089 (C.D. Cal. 2002).....	5
23	<i>Valentine v. Merck & Co.</i> ,	
24	2007 U.S. Dist. LEXIS 14531 (E.D. Cal. 2007)	11
25	<i>Von Grabe v. Sprint PCS</i> ,	
26	312 F. Supp. 2d 1285 (C.D. Cal. 2003).....	8, 10
27	<i>Western Mining Council v. Watt</i> ,	
28	643 F.2d 618 (9th Cir. 1981).....	6
	<u>STATUTES</u>	
	Cal. Civil Code §§ 1700, et seq	1
	Cal. Civil Code § 1782 (a)(1)	10
	Cal. Civil Code § 1761(a)	8
	Fed. R. Civ. P. 12(b)(6).....	5

I. SUMMARY OF ARGUMENT

This court should deny Plaintiffs' unfounded motion to remand as the settled law and uncontroverted facts establish that the two in-state Distributor Defendants, McKesson Corporation and Merry X-Ray Chemical Corporation have been fraudulently joined.¹ Specifically, the purported joinder is fraudulent because Plaintiffs have failed to state any plausible claim under either a tort theory or the California Legal Remedies Act ("CLRA"), as shown below:

- Plaintiffs' tort claims fail because California law does not recognize strict liability or negligent failure to warn causes of action against distributors in the prescription drug context.
- Plaintiffs' CLRA claims fail as a matter of law because CLRA does not apply to a distributor of non-consumer products, including the gadolinium-based contrast agents ("GBCA") at issue here.
- Plaintiffs' claims further fail under Supreme Court and California pleading requirements, as Plaintiffs' claims against the Distributor Defendants are devoid of facts depicting an unlawful method, act or practice.
- Plaintiffs also fail to demonstrate any causal connection between an alleged illegal act and any damages, and thus, are legally insufficient to establish a "plausible claim."²

¹ Defendants McKesson Corporation ("McKesson") and Merry X-Ray Chemical Corp. ("MXR") (collectively referred to as the "Distributor Defendants") are California wholesale distributors of various medical products, including gadolinium-based contrast agents. Neither of the Distributor Defendants manufacture, design, test, package, or label any GBCAs. Distributor Defendants merely fill orders from various facilities and sell the product in its original package, as received from the manufacturer. *See* declarations of Greg Yonko and Larry Lawson, attached to Defendant GE's Notice of Removal.

² *See Bell Atlantic Corp. v. Twombly*, -- U.S. ---, 127 S.Ct. 1955, 1965, 1974 (2007); Cal. Civ. Code §§ 1700, et seq.; *Oestreicher v. Alienware Corp.*, ---F. Supp. ---, No. C 07-00512 MHP, 2008 WL 906550 (N.D. Cal. Apr. 1, 2008) (applying the heightened pleading standard of *Bell v. Twombly* in a CLRA action, holding that a plaintiff must proffer "enough facts to state a claim to relief that is plausible on its face" and that conclusory, legal conclusions, unwarranted

- Plaintiffs, through their counsel, admit that neither McKesson nor MXR are necessary parties in the MDL proceeding before Judge Polster and that the MDL proceeding is a fair and available tribunal to handle such claims.³

For the reasons stated above, this Court should deny Plaintiffs' Motion to Remand. In the alternative, this Court should stay this case pending its transfer to MDL 1909, so that consistent rulings are applied to motions to remand substantially similar to the one Plaintiffs filed here.⁴

II. FACTS AND PROCEDURAL BACKGROUND

Plaintiffs filed their Complaint on March 5, 2008 in the Superior Court of California, County of San Francisco alleging that Mrs. Moorhouse suffers from

deductions of fact or unreasonable inferences do not state a plausible claim); *Int'l Norcent Tech. v. Koninklijke Philips Elect. N.V.*, No. CV07-00043MMM (SSx), 2007 WL 4976364, (C.D. Cal. Oct. 29, 2007) (applying the heightened pleading standard of *Bell v. Twombly* in an antitrust action, noting that a plaintiff must plead facts sufficient to give rise to a plausible claim, and "magic words" without factual support do not nudge a claim across the line from conceivable to plausible, and thus, does not suffice to state a claim).

³ In essence, Plaintiffs' counsel admit that neither McKesson nor MXR are necessary parties and this case is one that involves issues that are best resolved by the recently established Multi-District Litigation ("MDL") Court in the United States District Court, Northern District of Ohio, before the Hon. Dan A. Polster (*In Re: Gadolinium-Based Contrast Agent Products Liability Litigation*). For instance, this Defendant is aware of five other cases with nearly identical facts that were filed in federal court by the same Plaintiffs' counsel who filed this case. All five of the federally-filed cases have been transferred to MDL 1909: (*In Re: Gadolinium-Based Contrast Agent Products Liability Litigation*) without objection from Plaintiffs. See Complaints for *Beckwith v. Bayer*, et al, CV08-1369, (N.D. Cal.); *Osborn v. Bayer et al.* CV08-1368, (N.D. Cal.); *Paschal v. Bayer et al.*, CV08 1298, (N.D. Cal.); *Sanchez v. Bayer, et al.*, CV08-0973, (N.D. Cal); and *Seabold v. Bayer et al.*, CV08-1367, (N.D. Cal.), attached as Exhibits A through E to the Declaration of Aggie B. Lee.

⁴ As such, Defendants' previously filed Application for Stay should be granted, and a ruling on Plaintiffs' Motion to Remand deferred, to prevent potentially inconsistent rulings, in light of the pending transfer of this case to MDL Court. See *Johnson v. Merck & Company*, No. C 07-00067 WHA, 2007 WL 754882 (N.D. Cal. Mar. 8, 2007) (holding "the calculus changes somewhat when deference to a MDL court will further 'the uniformity, consistency, and predictability in litigation that underlies the MDL system.'"); *Leeson v. Merck & Company*, NO. S-05-2240 WBS (PAN), 2006 WL 3230047 *1 (E.D. Cal. Jan. 27, 2006) (quoting *Conroy v. Fresh Del Monte Produce, Inc.*, 325 F. Supp. 2d 1049, 1053 (N.D. Cal. 2004).

Nephrogenic Systemic Fibrosis (“NSF”) caused by GBCA(s) manufactured, marketed, sold and distributed by the manufacturing defendants. Using a shotgun approach, Plaintiffs named as Defendants all of the sponsors⁵ of GBCAs marketed in the U.S. But, in an attempt to create a lack of complete diversity, Plaintiffs also named two in-state Distributor Defendants to improperly undermine Defendants’ right to a federal forum.

On April 4, 2008, the diverse Defendants timely removed this case to federal court based on fraudulent joinder. On April 21, 2008, Defendants filed an Application to Stay Proceedings pending transfer to MDL 1909: *In Re: Gadolinium-Based Contrast Agent Products Liability Litigation*. Plaintiffs filed their Motion to Remand on April 22, 2008. Now, Defendant BDI furnishes this Court with indisputable legal authority that show remand should be denied, as Plaintiffs do not have any viable claims against the Distributor Defendants.

III. PLAINTIFFS’ CLAIMS FAIL TO STATE ANY LEGALLY PLAUSIBLE CLAIM(S)

There is not a single allegation in Plaintiffs’ Complaint of individualized conduct against the Distributor Defendants. Rather, *all* “Defendants” knew or should have known of the risks of the GBCA products, failed to warn Mrs. Moorhouse and her physicians of the risks, and have failed to advise consumers and/or healthcare providers of the risks. Pls.’ Compl. ¶¶ 55, 57.

Plaintiffs’ Complaint fails to link in any fashion the Distributor Defendants to the specific GBCA or GBCAs at issue. On the one hand, Plaintiffs’ Complaint identifies specific products for each sponsor named in the Complaint: (1)

⁵ A drug “sponsor” is the person or entity who assumes responsibility for the marketing of a new drug, including responsibility for compliance with applicable provisions of the *Federal Food, Drug and Cosmetic Act* and related regulations. The “sponsor” is usually an individual, partnership, corporation, government agency, manufacturer or scientific institution. (See: <http://www.fda.gov/cder/handbook/sponsor.htm>).

1 *Magnevist* as to Bayer, (2) *Omniscan* and *MRI and MRA machines* as to GEHC,
 2 (3) *OptiMARK* as to Tyco, (4) *MultiHance* and *ProHance* as to Bracco. *See* Pls.’
 3 Compl. ¶¶ 7, 13, 19, 23. On the other hand, Plaintiffs allege only *on information*
 4 *and belief that* (a) McKesson distributed *Omniscan and/or other gadolinium-based*
 5 *contrast agents* that were injected into Mrs. Moorhouse, and (b) Merry X-Ray
 6 distributed *Magnevist and/or other gadolinium-based contrast agents* that were
 7 injected into Mrs. Moorhouse. *See* Pls.’ Compl. ¶¶ 28, 31, 47.

8 Further, all allegations in Plaintiffs’ Complaint against the Distributor
 9 Defendants are derivative of claims against the defendant sponsors. The gravamen
 10 of the Complaint involves actions alleged to have been taken at the *pre-clinical*
 11 *stage* of development of the GBCA products. (“In pre-clinical studies during which
 12 gadolinium-based contrast agents were injected into laboratory animals, consistent
 13 patterns of toxicity including nephrogenic fibrotic changes in the kidneys and other
 14 body organs occurred”). *See* Pls.’ Compl. ¶ 48. Pre-clinical development is
 15 exclusively within the responsibility of the sponsor.

16 Finally, regarding the Sixth Cause of Action for Violation of the Consumer
 17 Legal Remedies Act (“CLRA”), the Complaint seeks monetary relief and is not, as
 18 represented in Plaintiffs’ Motion to Remand, limited to injunctive relief. Plaintiffs’
 19 Complaint seeks “any other relief this Court deems proper, and attorneys’ fees.”
 20 *See* Pls.’ Compl. ¶ 100.

21 **IV. ARGUMENT**

22 **A. THE FRAUDULENT JOINDER STANDARD UNDER THE** 23 **RECENT SUPREME COURT DECISION IN BELL ATLANTIC** 24 **V. TWOMBLY**

25 The standard for ruling on a motion to remand is substantially similar to the
 26 standard for a motion to dismiss under Federal Rule of Civil Procedure, 12(b)(6).
 27 A motion to dismiss for failure to state a claim tests the complaint’s legal
 28

1 sufficiency. Fed. R. Civ. P. 12(b)(6); *North Star Int'l v. Arizona Corp. Comm'n*,
 2 720 F.2d 578, 581 (9th Cir. 1983); *Roe III v. Unocal Corp.*, 70 F. Supp. 2d 1073,
 3 1075 (C.D. Cal. 1999). While the test for fraudulent joinder resembles a Rule
 4 12(b)(6) analysis in that the federal court accepts non-conclusory allegations as
 5 true, a court's inquiry is broader than Rule 12(b)(6). See *TPS Utilicom Services*,
 6 *Inc.*, 223 F. Supp. 2d 1089, 1102 (C.D. Cal. 2002). "The defendant seeking
 7 removal to the federal court is entitled to present the facts showing the joinder to
 8 be fraudulent." *Id.*, (citations omitted).

9 Clarifying the standard for a legally sufficient claim, the Supreme Court
 10 recently held that in order to state a claim for relief, a plaintiff must allege
 11 sufficient facts to state a "plausible" claim. *Bell Atlantic Corp. v. Twombly*, -- US
 12 ---, 127 S.Ct. 1955 (2007). The *Bell Atlantic* Court held that it abrogated the
 13 previous "*Conley* 'no set of facts' standard for 12(b)(6) motions (a standard also
 14 used for deciding remand). Under *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957),
 15 dismissal for failure to state a claim upon which relief may be granted required an
 16 appearance beyond a doubt that the plaintiff could prove no set of facts in support
 17 of a claim.

18 Under the *Bell Atlantic* standard, a plaintiff must state a "plausible claim" by
 19 providing factual allegations enough to raise a right of relief above the
 20 "speculative" level and provide grounds of his entitlement to relief. *Id.* Labels,
 21 conclusions and "formulaic recitation of the elements" will not suffice. *Id.* at
 22 1958-59; *Harara v. Landamerica Financial Group Inc.*, No. C 07-03999 WHA,
 23 2007 WL 2938172 at 4 (N.D. Cal. Oct. 9, 2007) (quoting *Bell Atlantic*, 127 S.Ct.
 24 1955).

25 Moreover, in order to state a plausible claim against any particular
 26 defendant, a plaintiff must allege facts of that particular defendant's involvement
 27
 28

1 in the allegedly illegal actions. *Choyce v. Saylor*, No. C-07-2394 PJH (PR), 2007
2 WL 3035406, at *2 (N.D. Cal. Oct. 16, 2007).

3 While the court must take as true all allegations of material fact in the light
4 most favorable to the non-moving party, a court need not “assume the truth of legal
5 conclusions merely because they are cast in the form of factual allegations.”
6 *Western Mining Council v. Watt*, 643 F.2d 618, 624 (9th Cir. 1981); *see also Parks*
7 *Sch. of Bus. v. Symington*, 51 F.3d 1480, 1484 (9th Cir. 1995).

8 As set forth below, Plaintiffs fail to plead a legally cognizable or “plausible”
9 claim on their tort and CLRA claims, and thus, this Court should deny remand
10 because no reasonable basis exists for proceeding against either of the non-diverse
11 Distributor Defendants.

12 **B. PLAINTIFFS FAIL TO ALLEGE ANY PLAUSIBLE CLAIM**
13 **AGAINST THE DISTRIBUTOR DEFENDANTS**

14 It is clear that Plaintiffs’ claims totally fail in two respects. First, there is no
15 allegation that the Plaintiff was actually exposed to a specific GBCA distributed by
16 either of the two Distributor Defendants.⁶ Alleging a factually unsupported
17 “possibility” does not meet the *Bell Atlantic* standard. Second and critically, there
18 is no and can be no causal nexus established as to any acts of the Distributor
19 Defendants and Plaintiffs’ claimed damages.⁷

23 ⁶ Plaintiffs make no specific allegation which of the five GBCA products, in any, were
24 allegedly used in Mrs. Moorhouse’s treatment, and thus futilely fails to make a specific claim
25 that GBCA used in her treatment was actually distributed by either McKesson or MXR.

26 ⁷ See *Aronis v. Merck & Co.*, 2005 U.S. Dist. LEXIS 41531 (E.D. Cal 2005) (holding
27 distributor McKesson found fraudulently joined in light of deficient complaint, noting “plaintiff
28 [did] not allege McKesson contributed in any way to her injuries, only that McKesson is a
distributor.”) Plaintiffs’ Complaint provides no nexus between the Distributor Defendants and
Mrs. Moorhouse’ injuries.

**1. PLAINTIFFS' TORT CLAIMS AGAINST THE
DISTRIBUTOR DEFENDANTS FAIL AS A MATTER OF
LAW**

Plaintiffs' claims against the Distributor Defendants for strict liability and negligent failure to warn fail as a matter of state law. In the context of prescription pharmaceutical products, no published California opinion has recognized a cause of action against distributors for failure to warn. *See* Pls.' Mot. To Remand p. 3, (citing *Black v. Merck & Company*, 2004 WL 754882 (N.D. Cal. March 8, 2007)).

Thus, most California federal district courts have ruled in a remand context that there is no viable cause of action against a non-diverse distributor defendant, including, but not limited to, Defendant McKesson, and that such distributors were fraudulently joined. *See Leeson v. Merck & Company*, 2006 WL 3230047 *3 (E.D. Cal. 2006).⁸

California law does not impose tort liability on distributors who do not manufacture, design or alter packaged pharmaceuticals. Therefore, the Distributor Defendants are "sham" defendants, wrongfully joined solely to defeat diversity jurisdiction and this Court should deny remand.

⁸ In denying the motion to remand where McKesson was joined as a non-diverse defendant, the *Leeson* Court noted that fraudulent joinder of McKesson (and other similarly situated distributor defendants) has been raised in numerous cases throughout California. *See id.* "Yet only a handful of judges have found that California law does not clearly exempt distributors from strict liability for failure to warn." *Id.* (referencing as Plaintiffs' relied upon exception *Black, supra*, (holding that Merck failed to show no possible claim against McKesson).) However, Plaintiffs' reliance on *Black* is misplaced and not applicable here, as *Black* was decided in 2004 and applied the less stringent and retired "*Conley* no set of facts" for a 12(b)(6) motion to dismiss standard, which has been abrogated by the Supreme Court holding in *Bell Atlantic*, discussed *supra*, Section A.

**2. PLAINTIFFS FAIL TO STATE A VIABLE CLRA CLAIM
AGAINST THE DISTRIBUTOR DEFENDANTS**

**a) Gadolinium-Based Contrast Agents are Not in the
Class of Products Covered by the CLRA**

Plaintiffs' Motion to Remand nonsensically asserts that the GBCA products at issue in this case were for Mrs. Moorhouse's "personal purpose," and such use "fits squarely within the definition of "goods" and thus within the purview of the CLRA." *See* Pls.' Mot. for Remand, p. 7.

It is undisputed that distributors of GBCAs *could not* make a direct sale of this prescription product to a patient such as Mrs. Moorhouse. GCBAs are prescribed by a physician (Pls.' Compl. ¶ 53) and are injected by trained medical personnel while a patient is under the care of a licensed imaging facility. They are not distributed over-the-counter, or sold to the public through licensed pharmacies. It is crystal clear that they are not consumer products under CLRA, namely, tangible chattel bought or leased for personal or household purposes (*see* Civil Code § 1761(a)) such items as bed linen (*Cattie v. Wal-mart Stores, Inc.*, 504 F. Supp. 2d 939 (S.D. Cal 2007)); cell phones (*Laster v. T-Mobile USA Inc.*, 407 F. Supp. 2d 1181 (S.D. Cal. 2005)); *Von Grabe v. Sprint PCS*, 312 F. Supp. 2d 1285 (C.D. Cal. 2003)); off-road vehicles (*Outboard Marine Corp. v. Superior Court*, 52 Cal.App.3d 30 (1975)); and store-sold salmon (*Farm Raised Salmon Cases*, 42 Cal.4th 1077 (2008)). Plaintiffs' claim to the contrary is patently ridiculous. This Court should deny remand, as Plaintiffs have not and cannot state a viable claim under the CLRA.

**b) Plaintiffs' CLRA Claims Against the Distributor
Defendants are Legally Insufficient**

Even if this Court were to allow a CLRA claim to proceed for the sale of a GBCA, Plaintiffs' claim must still fail. Plaintiffs fail to allege anything more than

1 a bare legal conclusion that the Distributor Defendants violated the CLRA without
 2 providing any facts whatsoever to “nudge its claims across the line from
 3 conceivable to plausible.” *Int’l Norcent*, 2007 WL 4976364 at *8 (quoting *Bell*
 4 *Atlantic*, 127 S. Ct. at 1974). Plaintiffs’ effort to finesse the issue falls flat.
 5 Plaintiffs state that in a blanket fashion that “Defendants” (which is meant to
 6 include all Defendants including the Distributor Defendants) violated the CLRA by
 7 conduct of marketing, promoting or selling Magnevist, Omniscan, OptiMark,
 8 MultiHance or ProHance for use in MRAs and other off-label uses by impliedly
 9 representing that such products are approved for use in MRAs and other off-label
 10 uses, when in fact there is no such approval, etc. *See* Pls.’ Compl. ¶ 97. Plaintiffs
 11 fail to allege any specific wrongful acts of the Distributor Defendants such as
 12 purported illegal actions, including as required, such detail as the time, place,
 13 person or any specific factual information that would give rise to a plausible claim.
 14 *See Choyce v. Saylor*, 2007 WL 3035406, at *2 (N.D. Cal. Oct. 16, 2007). It is
 15 unclear whether Mrs. Moorhouse even had an MRA, and if so, when, where, and
 16 what product was administered and by whom. No fact is pled to show a nexus or
 17 causal connection between the conduct allegedly at issue and plaintiffs’ claims for
 18 damages.

19 The Supreme Court in *Bell Atlantic* made clear that the federal rules have
 20 not “dispensed with the pleading of facts altogether. . . . Without some factual
 21 allegation in the complaint, it is hard to see how” a defendant could receive “fair
 22 notice of the nature of the claim, but also grounds on which the claims rest.” *Bell*
 23 *Atlantic*, 127 S.Ct. at 1965 n.3. Vague “notice” pleading is insufficient to plead a
 24 viable claim. As such, Plaintiffs’ CLRA claims against the Distributor Defendants
 25 must fail and the denial of remand is warranted.

**c) Plaintiffs Failed to Adhere to the Notice
Requirements of the CLRA**

Additionally, Plaintiffs' failure to comply with the notice provisions of the CLRA requires dismissal of the cause of action with prejudice. *See Laster*, 407 F. Supp. 2d at 1195-96; *Von Grabe*, 312 F. Supp. 2d at 1304; *Cattie*, 504 F. Supp. 2d 939. Section 1782 of the Cal. Civil Code mandates that 30 days before commencing a CLRA action, the plaintiff must "[n]otify the person alleged to have employed or committed methods, acts, or practices declared unlawful by Section 1770 of the particular alleged violations of 1770." (Cal. Civil Code § 1782 (a)(1).) The notice provisions of the CLRA are jurisdictional and must be applied literally. *See Outboard Marine Corp.*, 52 Cal.App.3d 30.

Plaintiffs admit they did not provide the required notice and erroneously argue that they are exempt because the Complaint seeks only injunctive relief. However, in their Sixth Cause of Action under the CLRA, Plaintiffs specifically request "injunctive relief, and any other relief this Court deems proper, and attorneys' fees." *See* Pls.' Compl. ¶ 100. In addition, *see* Prayer No. 2, applicable to all causes of action. Because Plaintiffs expressly seek non-injunctive relief, Section 1782(d) does not apply, and Plaintiffs' CLRA claims are barred.

**C. IN THE ALTERNATIVE, THIS COURT SHOULD STAY THIS
MATTER AND DEFER RULING ON THE REMAND MOTION**

Plaintiffs make an end run request to have their Motion to Remand ruled upon prior to the Court considering Defendants earlier filed Application for Stay pending transfer to the MDL. Such a request conflicts with the doctrines of judicial economy and equity. *See* Pls.' Opp'n to Stay App.

Judicial economy will be well-served by deferring ruling on Plaintiffs' Motion to Remand. Although it is true that generally, federal courts should resolve jurisdictional issues before determining whether a stay is appropriate, when

1 considering jurisdictional issues when an MDL has been established, “the calculus
 2 changes somewhat when deference to a MDL court will further ‘the uniformity,
 3 consistency, and predictability in litigation that underlies the MDL system.’”
 4 *Leeson v. Merck & Company*, 2006 WL 3230047 *1 (quoting *Conroy v. Fresh Del*
 5 *Monte Produce, Inc.*, 325 F. Supp. 2d 1049, 1053 (N.D. Cal. 2004); *Smith v. Mail*
 6 *Boxes, Etc.*, 191 F. Supp. 2d 1155, 1157 (E.D. Cal. 2002). Here, a transfer to the
 7 MDL is warranted.

8 It would be an inefficient use of resources to unnecessarily duplicate the
 9 efforts of the transferee judge, who will undoubtedly face most (if not all) of the
 10 same issues in dealing with the other pending remand motions. *Id.*; *see also*
 11 *Leeson v. Merck & Company*, 2006 WL 3230047 *1 (E.D. Cal. 2006) (stay granted
 12 prior to consideration of remand motion although transfer to MDL had not been
 13 ordered); *Hardin v. Merck & Co., Inc.*, 2007 WL 1056790 (N.D. Cal. 2007);
 14 *Valentine v. Merck & Co.*, 2007 U.S. Dist. LEXIS 14531 (E.D. Cal. 2007); *English*
 15 *v. Merck & Co.*, 2007 U.S. Dist. LEXIS 14493 (E.D. Cal. 2007); *Johnson v.*
 16 *Merck & Co.*, 2005 U.S. Dist. LEXIS 40703 (N.D. Cal. 2005); *Purcell v. Merck &*
 17 *Co.*, 2005 U.S. Dist. LEXIS 41239 (S.D. Cal. 2005); *Beatty v. Merck & Co.*, 2006
 18 U.S. Dist. LEXIS 77260 (E.D. Cal. 2006); *Cline v. Merck & Co.*, 2006 U.S. Dist.
 19 LEXIS 34417 (E.D. Cal. 2006).

20 Defendant BDI respectfully suggests that the prudent course would be to
 21 stay the case and allow the Hon. Dan A. Polster to issue consistent rulings on the
 22 all the cases where similar remand issues are pending – California, New Jersey and
 23 Louisiana. Otherwise, there will be a high likelihood of inconsistent rulings,
 24 duplicative work and inefficient use of precious judicial resources.

25 **V. CONCLUSION**

26 Plaintiffs have totally failed to provide any legal basis or factual support for
 27 any claims against the nonmanufacturing Distributor Defendants. California law
 28

1 provides no vehicle to impose liability on these defendants for the alleged
2 distribution of GBCAs. As such, Defendant BDI respectfully requests that this
3 Court deny Plaintiffs' Motion to Remand, or alternatively, stay this action pending
4 its transfer to MDL 1909 and defer, consistent with such a stay, any ruling on
5 Plaintiffs' Remand Motion.

6
7 DATED: MAY 20, 2008

TUCKER ELLIS & WEST LLP

8
9
10 By: /s/ Aggie B. Lee
11 Aggie B. Lee
Attorneys for Defendant
BRACCO DIAGNOSTICS INC.

12 Of Counsel:

13 Thomas N. Sterchi

14 Patrick Lysaught

15 Paul S. Penticuff

Elizabeth McCulley

16 BAKER STERCHI COWDEN & RICE, L.L.C.

2400 Pershing Road, Suite 500

17 Kansas City, MO 64108

18 Telephone: (816) 471-2121

19 Facsimile: (816) 472-0288
20
21
22
23
24
25
26
27
28

TUCKER ELLIS & WEST LLP
MICHAEL C. ZELLERS-STATE BAR NO. 146904
MOLLIE BENEDICT-STATE BAR NO. 187084
AGGIE B. LEE-STATE BAR NO. 228332
515 S. Flower Street, 42nd Floor
Los Angeles, CA 90071-2223
Telephone: (213) 430-3400
Facsimile: (213) 430-3409
michael.zellers@tuckerellis.com
mollie.benedict@tuckerellis.com
aggie.lee@tuckerellis.com

Attorneys for Defendant
BRACCO DIAGNOSTICS INC.

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA**

CAROL MOORHOUSE and JAMES
MOORHOUSE,

Plaintiffs,

v.

BAYER HEALTHCARE
PHARMACEUTICALS, INC.; BAYER
HEALTHCARE LLC; GENERAL
ELECTRIC COMPANY; GE
HEALTHCARE, INC.; COVIDIEN,
INC.; MALLINCKRODT, INC.;
BRACCO DIAGNOSTICS, INC.;
McKESSON CORPORATION;
MERRY X-RAY CHEMICAL CORP.;
and DOES 1 through 35,

Defendants.

Case No. CV-08-1831 SBA

**DECLARATION OF AGGIE B.
LEE IN SUPPORT OF
DEFENDANT BRACCO
DIAGNOSTICS INC.
OPPOSITION TO MOTION TO
REMAND**

[Filed Concurrently with BDI's
Opposition to Motion to Remand and
Proposed Order]

Date: June 10, 2008
Time : 1:00 p.m.
Courtroom: 3

DECLARATION OF AGGIE B. LEE IN SUPPORT OF DEFENDANT
BDI'S OPPOSITION TO MOTION TO REMAND

CV-08-1831 SBA

DECLARATION OF AGGIE B. LEE

I, Aggie B. Lee, declare as follows:

1. I am an attorney at law duly authorized to practice before the courts of the State of California and am admitted to the United States District Court, Northern District of California. I am an associate with the law firm of Tucker Ellis & West LLP, attorneys for Defendant Bracco Diagnostics Inc. ("BDI"). I have personal knowledge of all of the facts attested to in this declaration and could competently testify thereto if called as a witness in any legal proceeding.

2. On March 5, 2008, Plaintiffs Carol Moorhouse and James Moorhouse ("Plaintiffs") filed a complaint in the Superior Court of California, San Francisco County captioned as *Carol Moorhouse, et al. v. Bayer Healthcare Pharmaceuticals, Inc., et al.*, Case No. CGC-08-472878.

3. After service of this Complaint, this case was removed to United States District Court for the Northern District of California. BDI consented to such removal.

4. This lawsuit involves allegations that Plaintiff Carol Moorhouse contracted nephrogenic systemic fibrosis as a result of exposure to gadolinium-based MRI contrast agents allegedly manufactured by BDI and the other named defendants.

5. Counsel for Plaintiffs has filed five other lawsuits against BDI and other defendants in federal court alleging injuries as a result of exposure to gadolinium-based MRI contrast agents. These five other lawsuits have all been sent to the United States District Court for the Northern District of Ohio, for inclusion in MDL 1909: *In re Gadolinium Contrast Dyes Product Liability Litigation*.

6. Attached as Exhibit A is a true and correct copy of the Complaint filed in *Beckwith v. Bayer, et al*, CV08-1369 (N.D. Cal.).

2.

DECLARATION OF AGGIE B. LEE IN SUPPORT OF DEFENDANT BDI'S
OPPOSITION TO MOTION TO REMAND

CV-08-1831 SBA

EXHIBIT “A”

E67 E-filing

ORIGINAL
FILED
08 MAR 10 PM 4:08
U.S. DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

Lawrence J. Gornick (SBN 136290)
Debra DeCarli (SBN 237642)
LEVIN SIMES KAISER & GORNICK LLP
44 Montgomery Street, 36th Floor
San Francisco, CA 94104
Telephone: (415) 646-7160
Fax: (415) 981-1270
lgornick@lskg-law.com
ddecarli@lskg-law.com

Attorneys for Plaintiffs

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION**

**MONTIE BECKWITH and PETRA
BECKWITH,**

Plaintiffs,

vs.

**BAYER HEALTHCARE
PHARMACEUTICALS, INC.; BAYER
HEALTHCARE LLC; GENERAL ELECTRIC
COMPANY; GE HEALTHCARE, INC.;
COVIDIEN, INC.; MALLINCKRODT, INC.;
and BRACCO DIAGNOSTICS, INC.**

Defendants.

Case No:

CV 08

1369

ORIGINAL COMPLAINT

DEMAND FOR JURY TRIAL

JCS

Plaintiffs, Montie and Petra Beckwith, (hereinafter "Plaintiffs") allege as follows:

NATURE OF THE CASE

1. Plaintiff Montie Beckwith ("Mr. Beckwith" or "Plaintiff") has nephrogenic systemic fibrosis ("NSF"). NSF is an incurable, painful, and deadly disease. Mr. Beckwith contracted NSF as a result of receiving intravenous injections of gadolinium-based contrast agents manufactured by the Defendants. Gadolinium-based contrast agents are not safe for use in individuals such as Plaintiff who have impaired kidney function. Defendants represented that the gadolinium-based contrast agents were safe and failed to warn of the risks associated with gadolinium-based contrast agents.

JURISDICTION AND VENUE

2. This Court has jurisdiction pursuant to 28 USC § 1332. Plaintiffs are citizens of a state that is different from the states where Defendants are incorporated and have their respective principal

1 places of business. The amount in controversy for this case exceeds \$75,000. Venue pursuant to
 2 28 USC § 1391(c) is proper because Defendants have sufficient contacts within the City and County of
 3 San Francisco, California to subject each of them to personal jurisdiction.

4 INTRADISTRICT ASSIGNMENT

5 3. On information and belief, a substantial part of the events or omissions which give rise
 6 to the claim occurred in the County and City of San Francisco.

7 PARTIES

8 *Plaintiffs*

9 4. Montie Beckwith and his wife Petra Beckwith are residents of the State of Arkansas.

10 *Defendants*

11 5. Defendants Bayer HealthCare Pharmaceuticals, Inc. and Bayer Healthcare LLC (jointly
 12 referred to as "Bayer") manufacture, market, and sell Magnevist, a gadolinium-based contrast agent
 13 that, on information and belief, was injected into Plaintiff.

14 6. Defendant Bayer HealthCare LLC is a Delaware business entity with its principal place
 15 of business in New York.

16 7. Defendant Bayer HealthCare Pharmaceuticals, Inc. is a Delaware business entity with
 17 its principal place of business in New Jersey. Defendant Bayer HealthCare Pharmaceuticals, Inc. is
 18 the U.S.-based pharmaceuticals unit of Bayer Healthcare LLC.

19 8. At all times relevant to this complaint, Bayer was in the business of designing,
 20 licensing, manufacturing, distributing, selling, marketing, promoting, and introducing Magnevist into
 21 interstate commerce.

22 9. Defendants General Electric Company and GE Healthcare, Inc. (jointly referred to as
 23 "GE") manufacture, market, and sell Omniscan, a gadolinium-based contrast agent that, on
 24 information and belief, was injected into Plaintiff.

25 10. Defendant General Electric Company is a New York business entity with its principal
 26 place of business in Connecticut.

27 11. Defendant GE Healthcare, Inc. is a Delaware corporation with its principal place of
 28 business in New Jersey.

12. At all times relevant to this complaint, GE was in the business of designing, licensing, manufacturing, distributing, selling, marketing, promoting, and introducing Omniscan into interstate commerce.

13. Defendants Covidien Inc. and Mallinckrodt, Inc. (collectively referred to as "Covidien") manufacture, market, and sell OptiMARK, a gadolinium-based contrast agent that, on information and belief, was injected into Plaintiff.

14. Defendant Covidien, Inc. is a Delaware corporation with its principal place of business in New Hampshire.

15. Defendant Mallinckrodt, Inc. is a Delaware corporation with its principal place of business in Missouri. Mallinckrodt is a business unit of Covidien, Inc.

16. At all times relevant to this complaint, Covidien was in the business of designing, licensing, manufacturing, distributing, selling, marketing, promoting, and introducing OptiMARK into interstate commerce.

17. Defendant Bracco Diagnostics, Inc. ("Bracco") manufactures, markets, and sells MultiHance and ProHance, gadolinium-based contrast agents that, on information and belief, were injected into Plaintiff.

18. Bracco Diagnostics, Inc. is a Delaware corporation with its principal place of business in New Jersey.

19. At all times relevant to this complaint, Bracco was in the business of designing, licensing, manufacturing, distributing, selling, marketing, promoting, and introducing MultiHance and ProHance into interstate commerce.

20. The Bayer, GE, Covidien, and Bracco Defendants are collectively referred to as Defendants.

FACTS

21. Mr. Beckwith was diagnosed with NSF in or around April of 2007.

22. NSF is predominantly characterized by discoloration, thickening, tightening, and swelling of the skin after receiving a gadolinium-based contrast agent injection. These fibrotic and edematous changes produce muscular weakness and inhibit flexion and extension of joints, resulting in

1 contractures. NSF often progresses to painful inhibition of the ability to use the arms, legs, hands,
2 feet, and other joints. The skin changes that begin as darkened patches or plaques progress to a
3 "woody" texture and are accompanied by burning, itching, or severe pain in the areas of involvement.
4 NSF also progresses to a fibrotic or scarring condition of other body organs such as the lungs, heart,
5 liver, and musculature, and that can inhibit their ability to function properly and may lead to death.
6 NSF is a progressive disease for which there is no known cure.

7 23. NSF is a man-made disease. It only occurs in patients who have received a gadolinium-
8 based contrast agent.

9 24. Gadolinium is a highly toxic heavy metal. It does not occur naturally in the human
10 body. The only known route for gadolinium to enter the human body is injection of a gadolinium-
11 based contrast agent.

12 25. Because gadolinium is toxic, it has to be coated to keep it from coming in contact with
13 human tissue when injected. This coating process is called chelation.

14 26. Gadolinium is eliminated from the body by the kidneys. Gadolinium-based contrast
15 agents are not safe if the chelate separates from the gadolinium, which is what happens over time if
16 kidneys are not functioning properly. Individuals with impaired kidney function risk dechelation, and
17 cannot efficiently or quickly eliminate gadolinium from their bodies. Defendants never tested the
18 safety of their gadolinium-based contrast agents in individuals with kidney impairment.

19 27. On information and belief, the gadolinium-based contrast agents injected into Plaintiff
20 were manufactured by Defendants.

21 28. In pre-clinical studies during which gadolinium-based contrast agents were injected into
22 laboratory animals, consistent patterns of toxicity including nephrogenic fibrotic changes in the
23 kidneys and other body organs occurred.

24 29. During the years that Defendants have manufactured, marketed, distributed, sold, and
25 administered gadolinium-based contrast agents, there have been numerous case reports, studies,
26 assessments, papers, and other clinical data that have described and/or demonstrated NSF in
27 connection with the use of gadolinium-based contrast agents.

28 30. Plaintiff received MRIs and/or MRAs utilizing gadolinium-based contrast agents.

31. Plaintiff had impaired kidney function at the time he received his first injection of gadolinium-based contrast agent and continued to have impaired kidney function at the time he received each subsequent injection of gadolinium-based contrast agent.

32. During the time period when Plaintiff received injections of Defendants' gadolinium-based contrast agents, Defendants knew or should have known that the use of gadolinium-based contrast agents created a risk of serious bodily injury and death in patients with impaired kidney function.

33. Defendants failed to warn Plaintiff and his healthcare providers about the serious health risks associated with gadolinium-based contrast agents, and failed to disclose the fact that there were safer alternatives.

34. As a direct and proximate result of receiving injections of gadolinium-based contrast agents manufactured, marketed, distributed, and sold by Defendants, Plaintiff developed NSF.

35. Defendants have repeatedly and consistently failed to advise consumers and/or their healthcare providers of the causal relationship between gadolinium-based contrast agents and NSF in patients with kidney impairment. Defendants knew or should have known of the risk of NSF posed by gadolinium-based contrast agents to individuals with impaired kidney function years before they finally issued warnings.

36. It was not until September 2007 that Bayer, GE, Bracco, and Mallinckrodt finally sent letters to healthcare providers warning them of the risk of NSF to kidney impaired individuals who received MRIs using gadolinium-based contrast agents.

37. Had Plaintiff and/or his healthcare providers been warned about the risks associated with gadolinium-based contrast agents, he would not have been administered gadolinium-based contrast agents and would not have been afflicted with NSF.

38. As a direct and proximate result of Plaintiff being administered gadolinium-based contrast agents, he has suffered severe physical injury and pain and suffering, including, but not limited to, the effects of NSF. Plaintiff's physical injuries and pain and suffering will inevitably worsen over time and will in all likelihood lead to death.

39. As a direct and proximate result of being administered gadolinium-based contrast

agents, Plaintiffs suffered and continue to suffer significant mental anguish and emotional distress and will continue to suffer significant mental anguish and emotional distress in the future.

40. As a direct and proximate result of being administered gadolinium-based contrast agents, Plaintiffs have also incurred medical expenses and other economic damages and will continue to incur such expenses in the future.

DISCOVERY RULE & FRAUDULENT CONCEALMENT

41. The discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew or through the exercise of reasonable care and diligence should have known of the existence of their claims against all Defendants. The nature of Plaintiffs' injuries and damages, and their relationship to gadolinium-based contrast agents used in conjunction with MRIs and MRAs, was not discovered, and through reasonable care and due diligence could not have been discovered, by Plaintiffs, until a time less than two years before the filing of this Complaint. Therefore, under appropriate application of the discovery rule, Plaintiffs' suit was filed well within the applicable statutory limitations period.

42. Defendants are estopped from asserting a statute of limitations defense because all Defendants fraudulently concealed from Plaintiffs the nature of Plaintiffs' injury and the connection between the injury and all Defendants' tortious conduct.

FIRST CAUSE OF ACTION

STRICT LIABILITY: FAILURE TO WARN

43. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

44. Defendants' gadolinium-based contrast agents, and MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents, were defective due to inadequate warnings or instruction for use, both prior to marketing and post-marketing. Defendants knew or should have known that their products created significant risks of serious bodily harm and death to consumers. Defendants failed to adequately warn consumers and their healthcare providers of such risks.

45. Because of Defendants' failure to provide adequate warnings with their products, Plaintiff was injected with gadolinium-based contrast agents that the Defendants manufactured,

1 designed, sold, supplied, marketed or otherwise introduced into the stream of commerce. Those
2 gadolinium-based contrast agents are the legal cause of Plaintiff's physical injuries, harm, damages,
3 and economic loss. Plaintiffs will continue to suffer such harm, damages, and economic loss in the
4 future.

5 **SECOND CAUSE OF ACTION**

6 **STRICT LIABILITY: DESIGN DEFECT**

7 46. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

8 47. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of
9 gadolinium-based contrast agents, and MRI and MRA machines designed to be used in conjunction
10 with gadolinium-based contrast agents.

11 48. The gadolinium-based contrast agents manufactured and supplied by Defendants were
12 defective in design or formulation in that, when they left the hands of the Defendants, the foreseeable
13 risks of the products exceeded the benefits associated with their design or formulation, or were more
14 dangerous than an ordinary consumer would expect.

15 49. The foreseeable risks associated with the design or formulation of gadolinium-based
16 contrast agents, and MRI and MRA machines designed to be used in conjunction with gadolinium-
17 based contrast agents, include, but are not limited to, the fact that the design or formulation of
18 gadolinium-based contrast agents are more dangerous than a reasonably prudent consumer would
19 expect when used in an intended or reasonably foreseeable manner.

20 50. As a direct and proximate result of Plaintiff being administered gadolinium-based
21 contrast agents as manufactured, designed, sold, supplied, marketed, and introduced into the stream of
22 commerce by Defendants, Plaintiff has suffered physical injury, harm, damages, and economic loss
23 and will continue to suffer such harm, damages, and economic loss in the future.

24 **THIRD CAUSE OF ACTION**

25 **STRICT LIABILITY: FAILURE TO ADEQUATELY TEST**

26 51. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

27 52. Defendants advised consumers and the medical community that gadolinium-based
28 contrast agents were safe for use. Defendants failed to adequately test gadolinium-based contrast

1 agents with respect to their use by consumers with kidney impairment.

2 53. Had Defendants adequately tested the safety of gadolinium-based contrast agents for
3 use by consumers with kidney impairment and disclosed those results to the medical community or the
4 public, Plaintiff would not have been administered gadolinium-based contrast agents.

5 54. As a direct and proximate result of Defendants' failure to adequately test the safety of
6 gadolinium-based contrast agents and as a direct and proximate result of Plaintiff being administered
7 gadolinium-based contrast agents as manufactured, designed, sold, supplied, marketed, and introduced
8 into the stream of commerce by Defendants, Plaintiff has suffered physical injury, harm, damages, and
9 economic loss and will continue to suffer such harm, damages, and economic loss in the future.

10 **FOURTH CAUSE OF ACTION**

11 **NEGLIGENCE**

12 55. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

13 56. Defendants had a duty to exercise reasonable care in the design, formulation, testing,
14 manufacture, labeling, marketing, sale and/or distribution of gadolinium-based contrast agents and the
15 MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents.
16 In particular, they had a duty to assure that their products did not pose an unreasonable risk of bodily
17 harm and adverse events.

18 57. Defendants failed to exercise reasonable care in the design, formulation, manufacture,
19 sale, testing, marketing, or distribution of gadolinium-based contrast agents and the MRI and MRA
20 machines designed to be used in conjunction with gadolinium-based contrast agents in that they knew
21 or should have known that the products could cause significant bodily harm or death and were not safe
22 for use by certain types of consumers.

23 58. Defendants failed to exercise ordinary care in the labeling of gadolinium-based contrast
24 agents and the labeling of MRI and MRA machines designed to be used in conjunction with
25 gadolinium-based contrast agents and failed to issue to consumers and their health care providers
26 adequate warnings concerning the risks of serious bodily injury or death due to the use of gadolinium-
27 based contrast agents and the MRI and MRA machines designed to be used in conjunction with
28 gadolinium-based contrast agents.

59. Despite the fact that Defendants knew or should have known that gadolinium-based contrast agents and the MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents posed a serious risk of bodily harm to consumers, Defendants unreasonably continued to manufacture and market gadolinium-based contrast agents and the MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents for administration to MRI and MRA patients with kidney impairment and failed to exercise reasonable care with respect to post-sale warnings and instructions for safe use.

60. At all relevant times, it was foreseeable to Defendants that consumers like Plaintiff would suffer injury as a result of their failure to exercise ordinary care as described above.

61. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered physical injuries, harm, damages, and economic loss and will continue to suffer such harm, damages and economic loss in the future.

62. The foregoing acts, conduct and omissions of Defendants were vile, base, willful, malicious, wanton, oppressive, and fraudulent, and were done with a conscious disregard for the health, safety, and rights of Plaintiffs and other users of Defendants' products, and for the primary purpose of increasing Defendants' profits. As such, Plaintiffs are entitled to exemplary damages.

FIFTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

63. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

64. Defendants supplied the public and Plaintiff's healthcare providers with materially false and incomplete information with respect to the safety of their gadolinium-based contrast agents.

65. The false information supplied by Defendants was that gadolinium-based contrast agents were safe.

66. In supplying this false information, Defendants failed to exercise reasonable care.

67. The false information communicated by Defendants to Plaintiff and his healthcare providers was material and Plaintiff justifiably relied in good faith on the information to his detriment.

68. As a direct and proximate result of Defendants' misrepresentations, Plaintiff was administered gadolinium-based contrast agents and has suffered physical injury, harm, damages, and

1 economic loss and will continue to suffer such harm, damages, and economic loss in the future.

2 **SIXTH CAUSE OF ACTION**

3 **FRAUD**

4 69. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

5 70. Defendants knowingly and intentionally made materially false and misleading
6 representations to Plaintiff's healthcare providers and to the public, to the effect that gadolinium-based
7 contrast agents were safe for use and that their labeling, marketing, and promotional materials fully
8 described all known risks associated with their product.

9 71. Defendants' representations were in fact false. Gadolinium-based contrast agents are
10 not safe for use and Defendants' labeling, marketing, and promotional materials did not fully describe
11 all known risks of the products.

12 72. Defendants had actual knowledge that gadolinium-based contrast agents created an
13 unreasonable risk of serious bodily injury and death to consumers, especially patients with kidney
14 impairment.

15 73. Defendants knowingly and intentionally omitted this information from their labeling,
16 marketing, and promotional materials and instead, labeled, promoted, and marketed their products as
17 safe for use in order to increase and sustain sales.

18 74. When Defendants made representations that gadolinium-based contrast agents were
19 safe for use, they knowingly and intentionally concealed and withheld from Plaintiff, his healthcare
20 providers, and the public, the fact that their gadolinium-based contrast agents are not safe for use in
21 consumers with kidney impairment.

22 75. Defendants had a duty to disclose that gadolinium-based contrast agents are not safe for
23 use in patients with kidney impairment. Defendants had superior knowledge of these facts that were
24 material to Plaintiff and his healthcare providers' decisions to use gadolinium-based contrast agents.

25 76. Plaintiff and his healthcare providers reasonably and justifiably relied on the
26 Defendants' representations that gadolinium-based contrast agents were safe for human use and that
27 Defendants' labeling, marketing, and promotional materials fully described all known risks associated
28 with the products.

77. Plaintiff did not know and could not have learned of the facts that the Defendants omitted and suppressed. The facts suppressed and concealed by the Defendants are material. Had Plaintiff and his healthcare providers known that gadolinium-based contrast agents are not safe for use in patients with renal insufficiency, Plaintiff would not have been injected with gadolinium-based contrast agents.

78. As a direct and proximate result of Defendants' misrepresentations and concealment, Plaintiff was administered gadolinium-based contrast agents and has suffered physical injury, harm, damages and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

79. The foregoing acts, conduct, and omissions of Defendants were vile, base, willful, malicious, wanton, oppressive, and fraudulent, and were done with a conscious disregard for the health, safety, and rights of Plaintiff and other users of Defendants' products, and for the primary purpose of increasing Defendants' profits. As such Plaintiffs are entitled to exemplary damages.

SEVENTH CAUSE OF ACTION

FRAUD: CONCEALMENT, SUPPRESSION OR

OMISSION OF MATERIAL FACTS

80. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

81. Defendants omitted, suppressed, or concealed material facts concerning the dangers and risk associated with the use of their gadolinium-based contrast agents, including but not limited to the risks to patients with kidney impairment of developing NSF, and the fact that safer alternatives were available. Further, Defendants purposely downplayed and understated the serious nature of the risks associated with use of their gadolinium-based contrast agents in order to increase and sustain sales.

82. As a direct and proximate result of Defendants' concealment of material facts, Plaintiff was administered gadolinium-based contrast agents and has suffered physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

83. The foregoing acts, conduct, and omissions of Defendants were vile, base, willful, malicious, wanton, oppressive, and fraudulent, and were done with a conscious disregard for the health, safety, and rights of Plaintiff and other users of Defendants' products, and for the primary

1 purpose of increasing Defendants' profits. As such Plaintiffs are entitled to exemplary damages.

2 **EIGHTH CAUSE OF ACTION**

3 **BREACH OF EXPRESS WARRANTY**

4 84. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

5 85. Defendants expressly warranted that gadolinium-based contrast agents were safe and
6 effective.

7 86. The gadolinium-based contrast agents manufactured and sold by Defendants did not
8 conform to these express representations because they cause serious injury to consumers when
9 administered in recommended dosages.

10 87. As a direct and proximate result of Defendants' breach of warranty, Plaintiff has
11 suffered physical injury, harm, damages, and economic loss and will continue to suffer such harm,
12 damages, and economic loss in the future.

13 **NINTH CAUSE OF ACTION**

14 **BREACH OF IMPLIED WARRANTY**

15 88. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

16 89. At the time Defendants designed, manufactured, marketed, sold, and distributed
17 gadolinium-based contrast agents, Defendants knew of the use for which gadolinium-based contrast
18 agents was intended and impliedly warranted the product to be of merchantable quality and safe for
19 such use.

20 90. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether
21 gadolinium-based contrast agents were of merchantable quality and safe for their intended use and
22 upon Defendants' implied warranty as to such matters.

23 91. Contrary to such implied warranty, gadolinium-based contrast agents were not of
24 merchantable quality or safe for their intended use because the product was unreasonably dangerous as
25 described above.

26 92. As a direct and proximate result of Defendants' breach of warranty, Plaintiff has
27 suffered physical injury, harm, damages, and economic loss and will continue to suffer such harm,
28 damages, and economic loss in the future.

TENTH CAUSE OF ACTION

VIOLATION OF ARKANSAS CONSUMER PROTECTION STATUTES

93. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

94. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code Ann. §§ 4-8-101 *et seq.* including but not limited to the following:

a. Marketing, promoting or selling Magnevist, Omniscan, OptiMark, MultiHance, or ProHance for use with MRAs and other off-label uses by impliedly representing that such products are approved for use with MRAs and other off-label uses, when in fact there is no such approval;

b. Representing that gadolinium-based contrast agents are safe and effective for all patients, including patients with kidney impairment, when in fact they are not;

c. Representing that MRIs and MRAs using gadolinium-based contrast agents are safer or more effective than other imaging methods that do not require the use of gadolinium-based contrast agents when in fact they are not;

d. Marketing, promoting, or selling their products as safer or superior to other brands of gadolinium-based contrast agents;

e. Marketing, promoting or selling Magnevist, Omniscan, OptiMark, MultiHance, or ProHance as inert or with words to that effect;

f. Marketing, promoting or selling Magnevist, Omniscan, OptiMark, MultiHance, or ProHance for use with MRAs or other off-label uses by expressly or impliedly representing that they are safe for such use; and

g. Remaining silent despite their knowledge of the growing body of evidence regarding the danger of NSF and doing so because the prospect of huge profits outweighed health and safety issues.

As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive actions or practices, Plaintiff was administered gadolinium-based contrast agents and has suffered serious physician injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

/// /// /// ///

ELEVENTH CAUSE OF ACTION

LOSS OF CONSORTIUM

95. Plaintiff Petra Beckwith ("Mrs. Beckwith") incorporates by reference and realleges each paragraph set forth above.

96. Petra Beckwith is the wife of Montie Beckwith.

97. As a direct and proximate result of Defendants conduct, Mrs. Beckwith has been deprived of her husband's love, society, companionship, and services and has otherwise suffered loss, the extent of which will be more fully adduced at the trial of this matter.

WHEREFORE, Plaintiffs pray for relief as follows:

1. Compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, loss of consortium, and other non-economic damages in an amount to be determined at trial of this action;
2. Past and future medical expenses, income, and other economic damages in an amount to be determined at trial of this action;
3. Punitive damages in an amount to be determined at trial of this action;
4. Pre- and post-judgment interest;
5. Attorneys' fees, expenses, and costs; and
6. Such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury.

Respectfully submitted this 7th day of March, 2008.

LEVIN SIMES KAISER & GORNICK LLP

By: _____
Debra DeCarli, Esq.

LOSS OF CONSORTIUM

95. Plaintiff Petra Beckwith ("Mrs. Beckwith") incorporates by reference and realleges each paragraph set forth above.

96. Petra Beckwith is the wife of Montie Beckwith.

97. As a direct and proximate result of Defendants conduct, Mrs. Beckwith has been deprived of her husband's love, society, companionship, and services and has otherwise suffered loss, the extent of which will be more fully adduced at the trial of this matter.

WHEREFORE, Plaintiffs pray for relief as follows:

1. Compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, loss of consortium, and other non-economic damages in an amount to be determined at trial of this action;
2. Past and future medical expenses, income, and other economic damages in an amount to be determined at trial of this action;
3. Punitive damages in an amount to be determined at trial of this action;
4. Pre- and post-judgment interest;
5. Attorneys' fees, expenses, and costs; and
6. Such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury.

Respectfully submitted this 7th day of March, 2008.

LEVIN SIMES KAISER & GORNICK LLP


Debra DeCarli

WELCOME TO THE U.S. DISTRICT COURT, SAN FRANCISCO
OFFICE HOURS: 9:00 A.M. TO 4:00 P.M.
415.522.2000

www.cand.uscourts.gov

In Addition to the Local Rules, the Following Guidelines Have Been Provided to Ensure That the Filing Process Is Accomplished with Ease and Accuracy. For Additional Information or Assistance, Please Call the above Number During Office Hours.

1. Documents are to be filed in the Clerk's Office at the location of the chambers of the judge to whom the action has been assigned. We do not accept filings for cases assigned to judges or magistrate judges in the Oakland or San Jose division, per Civil L.R. 3-2(b).
2. This office will retain the original plus one copy of most documents submitted. We will conform as many copies as you bring for your use. Related cases require an extra copy for each related action designated.
3. The copy retained goes directly to the assigned Judge. Courtesy copies, or instructions for couriers to deliver a copy directly to chambers are inappropriate, unless you have been instructed to do so by court order.
4. In order to facilitate the file stamping process, each original document should be submitted on top of its copies. In other words, group like documents together--as opposed to a set of originals and separate sets of copies.
5. The case number must indicate whether it is a civil or criminal matter by the inclusion of **C** or **CR** at the beginning of the number. Miscellaneous and foreign judgment matters should also be indicated with initials **MISC** or **FJ** at the end of the case number.
6. The case number must include the initials of the judge and/or magistrate judge followed by the letters designating the case Arbitration (**ARB**), Early Neutral Evaluation (**ENE**) or Mediation (**MED**)--if assigned to one of those programs.
7. The document caption should include the appropriate judge or magistrate judge involved in a particular matter or before whom an appearance is being made. This is especially important when submitting Settlement Conference Statements.
8. Documents are to be stapled or acco-fastened at the top. Backings, bindings and covers are not required. Two holes punched at the top of the original document will facilitate processing.
9. Appropriately sized, stamped, self-addressed return envelopes are to be included with proposed orders or when filing documents by mail.

10. Proofs of service should be attached to the back of documents. If submitted separately, you must attach a pleading page to the front of the document showing case number and case caption.
11. There are no filing fees once a case has been opened.
12. New cases must be accompanied by a completed and signed Civil Cover Sheet, the filing fee or fee waiver request form and an original plus two copies of the complaint and any other documents. For Intellectual Property cases, please provide an original plus three copies of the complaint. Please present new cases for filing before 3:30 p.m., as they take a considerable amount of time to process.
13. Copies of forms may be obtained at no charge. They may be picked up in person from the Clerk's Office forms cabinet or with a written request accompanied by an appropriate sized, stamped, self-addressed envelope for return. In addition, copies of the Local Rules may be obtained, free of charge, in the Clerk's Office or by sending a written request, along with a self-addressed, 10" x 14" return envelope, stamped with \$ 3.95 postage to: Clerk, U.S. District Court, 450 Golden Gate Avenue, 16th Floor, San Francisco, CA 94102.
14. Two computer terminals which allow public access to case dockets and one terminal with information regarding files at the Federal Records Center (FRC) are located in the reception area of the Clerk's Office. Written instructions are posted by the terminals. Outside of the Clerk's Office, electronic access to dockets is available through PACER. To obtain information or to register call 1-800-676-6851.
15. A file viewing room is located adjacent to the reception area. Files may be viewed in this area after signing the log sheet and presenting identification. Files are to be returned by 1:00 pm. Under no circumstances are files to be removed from the viewing room.
16. The Clerk's Office can only accept payment by exact change or check made payable to Clerk, U.S. District Court. No change can be made for fees or the public copy machine.
17. Two pay copy machines are located in the file viewing room for public use, at fifteen cents (\$.15) per page. Copy cards may be purchased at the snack bar on the first floor. Orders for copywork may be placed through Eddie's Document Retrieval by phoning 415-317-5556. Arrangements may be made to bring in a personal copier by calling the Clerk's Office in advance.
18. We have a drop box for filing when the Clerk's Office is closed. Please see attached for availability and instructions.

SAN FRANCISCO

Article III Judges	Judges Initials	Magistrate Judges	Judges Initials
Alsup, William H.	WHA	Chen, Edward M.	EMC
Breyer, Charles R.	CRB	James, Maria-Elena	MEJ
Chesney, Maxine M.	MMC	Laporte, Elizabeth D.	EDL
Conti, Samuel	SC	Larson, James	JL
Hamilton, Phyllis J.	PJH	Spero, Joseph C.	JCS
Henderson, Thelton E.	TEH	Zimmerman, Bernard	BZ
Illston, Susan	SI		
Jenkins, Martin J.	MJJ		
Patel, Marilyn Hall	MHP		
Schwarzer, William W	WWS		
Walker, Vaughn R	VRW		
White, Jeffrey S.	JSW		

SAN JOSE

Article III Judges	Judges Initials	Magistrate Judges	Judges Initials
Fogel, Jeremy	JF	Lloyd, Howard R.	HRL
Ware, James	JW	Seeborg, Richard	RS
Whyte, Ronald M.	RMW	Trumbull, Patricia V.	PVT

OAKLAND

Article III Judges	Judges Initials	Magistrate Judges	Judges Initials
Armstrong, Sandra B.	SBA	Brazil, Wayne D.	WDB
Jensen, D. Lowell	DLJ		
Wilken, Claudia	CW		

San Francisco	16th Floor	building closed between 6PM and 6AM	more info 415-522-2000
San Jose	2nd Floor	building closed between 5PM and 7:30AM	more info 408-535-5364
Oakland	1st Floor	building closed between 5:00 PM and 7:00 AM	more info 510-637-3530

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

DROP BOX FILING PROCEDURES

1. The drop box, located outside the Clerk's Office (see above chart), is available for the filing of documents before 9:00 a.m. and after 4:00 p.m. weekdays. Please note that access to the federal building is limited to 'normal business hours' (as noted in the chart above).
2. The drop box may not be used for the filing of any briefs in support of, or in opposition to, any matter scheduled for a hearing within 7 calendar days. All such documents must be filed in the Clerk's Office during regular office hours by the date due.
3. Using the electronic file stamping machine located next to the drop box, stamp each original document "Received" on the back side of the last page. Clerk's Office employees empty the box once each court day when the Clerk's Office opens to the public. The "Filed" date, which will be placed on original documents by Intake personnel, will be the same as the "Received" date, unless the "Received" date is a weekend or Court holiday. In those instances, the "Filed" date will be the first court day following the weekend or holiday. Documents placed in the drop box without a "Received" stamp will be filed as of the day the box is next emptied.
4. After stamping each original and enclosing one copy for the court,* the documents must be placed in an orange court mailing pouch or red Expando folder provided for your convenience. *To facilitate processing of your documents, each original document should be submitted on top of its copies.* Prior to placing the pouch or folder in the drop box, please insert in the pouch or folder window a fully completed **Drop Box Filing Information Card**. You may use more than one pouch or folder per filing, *but a separate Information Card must be enclosed for each one.*
(*Please note that the Clerk's Office will retain two copies of all new complaints relating to patents, trademarks and copyrights.)
5. If you wish us to mail you one or more conformed copies that you have provided, you must enclose an appropriately sized, self-addressed, stamped envelope with adequate return postage. Alternatively, if you would like to pick up conformed copies, please mark your return envelope **"FOR MESSENGER PICK UP BY: (NAME, FIRM)."** Your copies will be available for pick-up after 2:00 p.m. on the day the drop box is emptied.
6. A filing fee, if required, may be paid by check or money order, payable to "Clerk, U.S. District Court" in an exact amount. *Please do not enclose cash.*
7. Documents deposited in the drop box must be in compliance with all local and federal rules, as appropriate. Documents filed "Under Seal" must be submitted in compliance with Civil L.R. 79-5.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

NOTICE OF ASSIGNMENT OF CASE
TO A UNITED STATES MAGISTRATE JUDGE FOR TRIAL

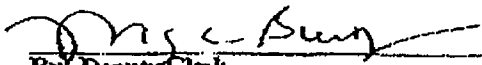
Pursuant to General Order 44, the Assignment Plan of the United States District Court for the Northern District of California, this case has been randomly assigned to Magistrate Judge JOSEPH C. SPERO

Pursuant to Title 28 U.S.C. § 636(c), with written consent of all parties, a magistrate judge may conduct all proceedings in the case. Attached is a form to complete if you consent to proceed before the assigned magistrate judge and a form to complete if you decline to proceed before the assigned magistrate judge. Electronic versions of both forms are also available at the Court's Internet site: <http://www.cand.uscourts.gov>. Click on Forms-Civil. A party is free to withhold consent without adverse consequences. If a party declines to consent, the case will be randomly reassigned to a district judge and a case management conference will be scheduled on the district judge's calendar as close as possible to the date presently scheduled before the magistrate judge.

You must file your consent or declination by the deadline for filing the initial case management statement.

The plaintiff or removing party shall serve a copy of this notice and all attachments upon all other parties to this action pursuant to Federal Rules of Civil Procedure 4 and 5.

FOR THE COURT
RICHARD W. WIEKING, CLERK


By: Deputy Clerk

MARY ANN BUCKLEY

1
2
3
4
5
6 UNITED STATES DISTRICT COURT
7 NORTHERN DISTRICT OF CALIFORNIA
8

9 No. C

10 Plaintiff(s),
11 y.

12 CONSENT TO PROCEED BEFORE A
UNITED STATES MAGISTRATE JUDGE

13 Defendant(s).
14

15 CONSENT TO PROCEED BEFORE A UNITED STATES MAGISTRATE JUDGE

16 In accordance with the provisions of Title 28, U.S.C. Section 636(c), the undersigned party
17 hereby voluntarily consents to have a United States Magistrate Judge conduct any and all further
18 proceedings in the case, including trial, and order the entry of a final judgment. Appeal from the
19 judgment shall be taken directly to the United States Court of Appeals for the Ninth Circuit.
20

21 Dated: _____

22 Signature _____

23 Counsel for _____
24 (Plaintiff, Defendant or indicate "pro se")
25
26
27
28

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

No. C

Plaintiff(s),

v.

Defendant(s).

DECLINATION TO PROCEED BEFORE
A MAGISTRATE JUDGE
AND
REQUEST FOR REASSIGNMENT TO A
UNITED STATES DISTRICT JUDGE

REQUEST FOR REASSIGNMENT TO A UNITED STATES DISTRICT JUDGE

The undersigned party hereby declines to consent to the assignment of this case to a United States Magistrate Judge for trial and disposition and hereby requests the reassignment of this case to a United States District Judge.

Dated: _____

Signature: _____

Counsel for
(Plaintiff, Defendant, or indicate "pro se")

E-filing

CV 08

1369

JCS

U.S. District Court Northern California

ECF Registration Information Handout

The case you are participating in has been designated for this court's Electronic Case Filing (ECF) Program, pursuant to Civil Local Rule 5-4 and General Order 45. This means that you must (check off the boxes ☒ when done):

- ☐ 1) Serve this ECF Registration Information Handout on all parties in the case along with the complaint, or for removals, the removal notice. DO NOT serve the efiler application form, just this handout.

Each attorney representing a party must also:

- ☐ 2) Register to become an efiler by filling out the efiler application form. Follow ALL the instructions on the form carefully. If you are already registered in this district, do not register again, your registration is valid for life on all ECF cases in this district.
- ☐ 3) Email (do not efile) the complaint and, for removals, the removal notice and all attachments, in PDF format within ten business days, following the instructions below. You do not need to wait for your registration to be completed to email the court.
- ☐ 4) Access dockets and documents using PACER (Public Access to Court Electronic Records). If your firm already has a PACER account, please use that - it is not necessary to have an individual account. PACER registration is free. If you need to establish or check on an account, visit: <http://pacer.uscourts.gov> or call (800) 676-6856.

BY SIGNING AND SUBMITTING TO THE COURT A REQUEST FOR AN ECF USER ID AND PASSWORD, YOU CONSENT TO ENTRY OF YOUR E-MAIL ADDRESS INTO THE COURT'S ELECTRONIC SERVICE REGISTRY FOR ELECTRONIC SERVICE ON YOU OF ALL E-FILED PAPERS, PURSUANT TO RULES 77 and 5(b)(2)(D) (eff. 12.1.01) OF THE FEDERAL RULES OF CIVIL PROCEDURE.

All subsequent papers submitted by attorneys in this case shall be filed electronically. Unrepresented litigants must file and serve in paper form, unless prior leave to file electronically is obtained from the assigned judge.

ECF registration forms, interactive tutorials and complete instructions for efilng may be found on the ECF website: <http://ecf.cand.uscourts.gov>

Submitting Initiating Documents

PDF versions of all the initiating documents originally submitted to the court (Complaint or Notice of Removal, exhibits, etc.) must be emailed (not efiled) to the PDF email box for the presiding judge (not the referring judge, if there is one) within 10 (ten) business days of the opening of your case. For a complete list of the email addresses, please go to: <http://ecf.cand.uscourts.gov> and click on [Judges].

You must include the case number and judge's initials in the subject line of all relevant emails to the court. You do not need to wait for your registration to email these documents.

These documents must be emailed instead of e-filed to prevent duplicate entries in the ECF system. All other documents must be e-filed from then on. You do not need to efile or email the Civil Cover Sheet, Summons, or any documents issued by the court at case opening; note that you do need to efile the Summons Returned.

Converting Documents to PDF

Conversion of a word processing document to a PDF file is required before any documents may be submitted to the Court's electronic filing system.

Instructions for creating PDF files can be found at the ECF web site:

<http://ecf.cand.uscourts.gov>, and click on [FAQ].

Email Guidelines: When sending an email to the court, the subject line of the email must contain the case number, judge's initials and the type of document(s) you are sending, and/or the topic of the email.

Examples: The examples below assume your case number is 03-09999 before the Honorable Charles R. Breyer:

Type of Document	Email Subject Line Text
Complaint Only	03-09999 CRB Complaint
Complaint and Notice of Related Case	03-09999 CRB Complaint, Related Case
Complaint and Motion for Temporary Restraining Order	03-09999 CRB Complaint, TRO

Questions

Almost all questions can be answered in our FAQs at <http://ecf.cand.uscourts.gov>, please check them first.

You may also email the ECF Help Desk at ECFhelpdesk@cand.uscourts.gov or call the toll-free ECF Help Desk number at: (866) 638-7829.

The ECF Help Desk is staffed Mondays through Fridays from 9:00am to 4:00pm Pacific time, excluding court holidays.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

E-filing

MONTIE BECKWITH,

Plaintiff(s),

v.

BAYER HEALTHCARE,
Defendant(s).

No. C 08-01369 JCS

ORDER SETTING INITIAL CASE
MANAGEMENT CONFERENCE
AND ADR DEADLINES

IT IS HEREBY ORDERED that this action is assigned to the Honorable Joseph C. Spero. When serving the complaint or notice of removal, the plaintiff or removing defendant must serve on all other parties a copy of this order, the Notice of Assignment of Case to a United States Magistrate Judge for Trial, and all other documents specified in Civil Local Rule 4-2. Counsel must comply with the case schedule listed below unless the Court otherwise orders.

IT IS FURTHER ORDERED that this action is assigned to the Alternative Dispute Resolution (ADR) Multi-Option Program governed by ADR Local Rule 3. Counsel and clients shall familiarize themselves with that rule and with the material entitled "Dispute Resolution Procedures in the Northern District of California" on the Court ADR Internet site at www.adr.cand.uscourts.gov. A limited number of printed copies are available from the Clerk's Office for parties in cases not subject to the court's Electronic Case Filing program (ECF).

CASE SCHEDULE -ADR MULTI-OPTION PROGRAM

Date	Event	Governing Rule
3/10/2008	Complaint filed	
5/23/2008	*Last day to: • meet and confer re: initial disclosures, early settlement, ADR process selection, and discovery plan • file Joint ADR Certification with Stipulation to ADR Process or Notice of Need for ADR Phone Conference	<u>FRCivP 26(f) & ADR L.R. 3-5</u> <u>Civil L.R. 16-8</u>
6/6/2008	*Last day to file Rule 26(f) Report, complete initial disclosures or state objection in Rule 26(f) Report and file Case Management Statement per attached Standing Order re Contents of Joint Case Management Statement (also available at http://www.cand.uscourts.gov)	<u>FRCivP 26(a) (1)</u> <u>Civil L.R. 16-9</u>
6/13/2008	INITIAL CASE MANAGEMENT CONFERENCE (CMC) in Ctrm A, 15th Floor, SF at 1:30 PM	<u>Civil L.R. 16-10</u>

* If the Initial Case Management Conference is continued, the other deadlines are continued accordingly.

EXHIBIT

A PAGE 29

STANDING ORDER

1
2
3 1. Civil Law and Motion is heard on Fridays, at 9:30 a.m. Criminal Law and
4 Motion is heard on Fridays, at 10:30 a.m. Counsel need not reserve a hearing date in advance
5 for civil motions. However, noticed dates may be reset as the Court's calendar requires.
6

7 2. Case Management and Pretrial Conferences are heard on Fridays, at 1:30 p.m.
8 Case Management Conferences will no longer be recorded, unless requested by the parties.
9

10 3. In cases that are randomly assigned to Judge Spero for all purposes, a Consent to
11 Proceed before a U.S. Magistrate Judge and a Declination to Proceed Before a Magistrate Judge
12 And Request For Reassignment to a United States District Judge Forms will be mailed to all
13 parties. The parties are requested, within two weeks from receipt of the form, to complete and
14 file the form indicating their consent or request for reassignment to a District Judge.
15

16 4. Parties with questions regarding scheduling of settlement conferences should
17 contact Judge Spero's secretary, Mary Ann Macudzinski-Gomez, at (415) 522-3691. All other
18 scheduling questions should be addressed to Judge Spero's courtroom deputy, Karen Horn, at
19 (415) 522-2035.
20

21 5. In lieu of filing formal discovery motions, lead trial counsel for Plaintiff(s) and
22 lead trial counsel for Defendant(s) shall meet and confer in person regarding the subject matter
23 of the Motion(s) in an effort to resolve these matters. After attempting other means to confer on
24 the issue (i.e. letter, phone call, e-mail) any party may demand such a meeting on ten (10)
25 business days' notice. The location of the meeting will alternate with the first location selected
26 by counsel for Plaintiff, the second by counsel for Defendant, etc. Within five (5) business days
27 of the lead trial counsels' meet-and-confer session, the parties shall provide a detailed Joint
28 Letter to the Court. This Joint Letter shall include a description of every issue in dispute and,

1 with respect to each such issue, a detailed summary of each party's final substantive position
2 and their final proposed compromise on each issue. Upon receipt of the Joint Letter the Court
3 will determine what future proceedings are necessary.

4
5 6. In all "e-filing" cases, when filing papers in connection with any motion for
6 determination by a judge, the parties shall, in addition to filing papers electronically, lodge with
7 chambers a printed copy of the papers by the close of the next court day following the day the
8 papers are filed electronically. These printed copies shall be marked "Chambers Copy" and
9 shall be submitted directly to Magistrate Judge Spero's chambers in an envelope clearly
10 marked with the judge's name, case number and "E-Filing Chambers Copy." Parties
11 shall not file a paper copy of any document with the Clerk's Office that has already been
12 filed electronically.

13
14 7. Any proposed stipulation or proposed order in a case subject to electronic filing
15 shall be sent by email to jcspe@cand.uscourts.gov. This address is to be used only for
16 proposed orders unless otherwise directed by the Court.

17 IT IS SO ORDERED.

18
19 Dated: May 29, 2007

20
21 
22 JOSEPH C. SPERO
23 United States Magistrate Judge
24
25
26
27
28

1
2
3
4 UNITED STATES DISTRICT COURT
5 NORTHERN DISTRICT OF CALIFORNIA
6
7

8 NOTICE OF RULE DISCONTINUING SERVICE BY MAIL
9

10 This is an E-filing case. Pursuant to Local Rule, the Court will no longer serve any counsel
11 by mail. If counsel wish to be served with documents generated by the Court, they must register for
12 E-filing pursuant to Local Rule 5-4 and General Order 45.

13 IT IS SO ORDERED.
14

15 Dated: May 30, 2003
16

17 
18 JOSEPH C. SPERO
19 United States Magistrate Judge
20
21
22
23
24
25
26
27
28

STANDING ORDER FOR ALL JUDGES OF THE NORTHERN DISTRICT OF CALIFORNIA

CONTENTS OF JOINT CASE MANAGEMENT STATEMENT

Commencing March 1, 2007, all judges of the Northern District of California will require the identical information in Joint Case Management Statements filed pursuant to Civil Local Rule 16-9. The parties must include the following information in their statement which, except in unusually complex cases, should not exceed ten pages.

1. Jurisdiction and Service: The basis for the court's subject matter jurisdiction over plaintiff's claims and defendant's counterclaims, whether any issues exist regarding personal jurisdiction or venue, whether any parties remain to be served, and, if any parties remain to be served, a proposed deadline for service.
2. Facts: A brief chronology of the facts and a statement of the principal factual issues in dispute.
3. Legal Issues: A brief statement, without extended legal argument, of the disputed points of law, including reference to specific statutes and decisions.
4. Motions: All prior and pending motions, their current status, and any anticipated motions.
5. Amendment of Pleadings: The extent to which parties, claims, or defenses are expected to be added or dismissed and a proposed deadline for amending the pleadings.
6. Evidence Preservation: Steps taken to preserve evidence relevant to the issues reasonably evident in this action, including interdiction of any document-destruction program and any ongoing erasures of e-mails, voice mails, and other electronically-recorded material.
7. Disclosures: Whether there has been full and timely compliance with the initial disclosure requirements of Fed. R. Civ. P. 26 and a description of the disclosures made.
8. Discovery: Discovery taken to date, if any, the scope of anticipated discovery, any proposed limitations or modifications of the discovery rules, and a proposed discovery plan pursuant to Fed. R. Civ. P. 26(f).
9. Class Actions: If a class action, a proposal for how and when the class will be certified.
10. Related Cases: Any related cases or proceedings pending before another judge of this court, or before another court or administrative body.
11. Relief: All relief sought through complaint or counterclaim, including the amount of any

-1-

damages sought and a description of the bases on which damages are calculated. In addition, any party from whom damages are sought must describe the bases on which it contends damages should be calculated if liability is established.

12. Settlement and ADR: Prospects for settlement, ADR efforts to date, and a specific ADR plan for the case, including compliance with ADR L.R. 3-5 and a description of key discovery or motions necessary to position the parties to negotiate a resolution.
13. Consent to Magistrate Judge For All Purposes: Whether all parties will consent to have a magistrate judge conduct all further proceedings including trial and entry of judgment.
14. Other References: Whether the case is suitable for reference to binding arbitration, a special master, or the Judicial Panel on Multidistrict Litigation.
15. Narrowing of Issues: Issues that can be narrowed by agreement or by motion, suggestions to expedite the presentation of evidence at trial (e.g., through summaries or stipulated facts), and any request to bifurcate issues, claims, or defenses.
16. Expedited Schedule: Whether this is the type of case that can be handled on an expedited basis with streamlined procedures.
17. Scheduling: Proposed dates for designation of experts, discovery cutoff, hearing of dispositive motions, pretrial conference and trial.
18. Trial: Whether the case will be tried to a jury or to the court and the expected length of the trial.
19. Disclosure of Non-party Interested Entities or Persons: Whether each party has filed the "Certification of Interested Entities or Persons" required by Civil Local Rule 3-16. In addition, each party must restate in the case management statement the contents of its certification by identifying any persons, firms, partnerships, corporations (including parent corporations) or other entities known by the party to have either: (i) a financial interest in the subject matter in controversy or in a party to the proceeding; or (ii) any other kind of interest that could be substantially affected by the outcome of the proceeding.
20. Such other matters as may facilitate the just, speedy and inexpensive disposition of this matter.

EXHIBIT “B”

EGM

U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO, CA 94104
FILED MAY 20 2008

Lawrence J. Gornick (SBN 136290)
Debra DeCarli (SBN 237642)
LEVIN SIMES KAISER & GORNICK LLP
44 Montgomery Street, 36th Floor
San Francisco, CA 94104
Telephone: (415) 646-7160
Fax: (415) 981-1270
lgornick@lskg-law.com
ddecarli@lskg-law.com

E-filing

Attorneys for Plaintiffs

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION**

AMY OSBORN and MICHAEL OSBORN,

Plaintiffs,

vs.

BAYER HEALTHCARE
PHARMACEUTICALS, INC.; BAYER
HEALTHCARE LLC; GENERAL ELECTRIC
COMPANY; GE HEALTHCARE, INC.;
COVIDIEN, INC.; MALLINCKRODT, INC.;
and BRACCO DIAGNOSTICS, INC.

Defendants.

CV 08

1368

Case No:

EDL

ORIGINAL COMPLAINT

DEMAND FOR JURY TRIAL

Plaintiffs, Amy Osborn and Michael Osborn, (hereinafter "Plaintiffs") allege as follows:

NATURE OF THE CASE

1. Plaintiff Amy Osborn ("Mrs. Osborn" or "Plaintiff") has nephrogenic systemic fibrosis ("NSF"). NSF is an incurable, painful, and deadly disease. Mrs. Osborn contracted NSF as a result of receiving intravenous injections of gadolinium-based contrast agents manufactured by the Defendants. Gadolinium-based contrast agents are not safe for use in individuals such as Plaintiff who have impaired kidney function. Defendants represented that the gadolinium-based contrast agents were safe and failed to warn of the risks associated with gadolinium-based contrast agents.

JURISDICTION AND VENUE

2. This Court has jurisdiction pursuant to 28 USC § 1332. Plaintiffs are citizens of a state that is different from the states where Defendants are incorporated and have their respective principal

1 places of business. The amount in controversy for this case exceeds \$75,000. Venue pursuant to
 2 28 USC § 1391(c) is proper because Defendants have sufficient contacts within the City and County of
 3 San Francisco, California to subject each of them to personal jurisdiction.

4 INTRADISTRICT ASSIGNMENT

5 3. On information and belief, a substantial part of the events or omissions which give rise
 6 to the claim occurred in the County and City of San Francisco.

7 PARTIES

8 *Plaintiffs*

9 4. Amy Osborn and her husband Michael Osborn are residents of the State of Georgia.

10 *Defendants*

11 5. Defendants Bayer HealthCare Pharmaceuticals, Inc. and Bayer Healthcare LLC (jointly
 12 referred to as "Bayer") manufacture, market, and sell Magnevist, a gadolinium-based contrast agent
 13 that, on information and belief, was injected into Plaintiff.

14 6. Defendant Bayer HealthCare LLC is a Delaware business entity with its principal place
 15 of business in New York.

16 7. Defendant Bayer HealthCare Pharmaceuticals, Inc. is a Delaware business entity with
 17 its principal place of business in New Jersey. Defendant Bayer HealthCare Pharmaceuticals, Inc. is
 18 the U.S.-based pharmaceuticals unit of Bayer Healthcare LLC.

19 8. At all times relevant to this complaint, Bayer was in the business of designing,
 20 licensing, manufacturing, distributing, selling, marketing, promoting, and introducing Magnevist into
 21 interstate commerce.

22 9. Defendants General Electric Company and GE Healthcare, Inc. (jointly referred to as
 23 "GE") manufacture, market, and sell Omniscan, a gadolinium-based contrast agent that, on
 24 information and belief, was injected into Plaintiff.

25 10. Defendant General Electric Company is a New York business entity with its principal
 26 place of business in Connecticut.

27 11. Defendant GE Healthcare, Inc. is a Delaware corporation with its principal place of
 28 business in New Jersey.

12. At all times relevant to this complaint, GE was in the business of designing, licensing, manufacturing, distributing, selling, marketing, promoting, and introducing Omniscan into interstate commerce.

13. Defendants Covidien Inc. and Mallinckrodt, Inc. (collectively referred to as "Covidien") manufacture, market, and sell OptiMARK, a gadolinium-based contrast agent that, on information and belief, was injected into Plaintiff.

14. Defendant Covidien, Inc. is a Delaware corporation with its principal place of business in New Hampshire.

15. Defendant Mallinckrodt, Inc. is a Delaware corporation with its principal place of business in Missouri. Mallinckrodt is a business unit of Covidien, Inc.

16. At all times relevant to this complaint, Covidien was in the business of designing, licensing, manufacturing, distributing, selling, marketing, promoting, and introducing OptiMARK into interstate commerce.

17. Defendant Bracco Diagnostics, Inc. ("Bracco") manufactures, markets, and sells MultiHance and ProHance, gadolinium-based contrast agents that, on information and belief, were injected into Plaintiff.

18. Bracco Diagnostics, Inc. is a Delaware corporation with its principal place of business in New Jersey.

19. At all times relevant to this complaint, Bracco was in the business of designing, licensing, manufacturing, distributing, selling, marketing, promoting, and introducing MultiHance and ProHance into interstate commerce.

20. The Bayer, GE, Covidien, and Bracco Defendants are collectively referred to as Defendants.

FACTS

21. Mrs. Osborn was diagnosed with NSF in or around April of 2006.

22. NSF is predominantly characterized by discoloration, thickening, tightening, and swelling of the skin after receiving a gadolinium-based contrast agent injection. These fibrotic and edematous changes produce muscular weakness and inhibit flexion and extension of joints, resulting in

1 contractures. NSF often progresses to painful inhibition of the ability to use the arms, legs, hands,
2 feet, and other joints. The skin changes that begin as darkened patches or plaques progress to a
3 "woody" texture and are accompanied by burning, itching, or severe pain in the areas of involvement.
4 NSF also progresses to a fibrotic or scarring condition of other body organs such as the lungs, heart,
5 liver, and musculature, and that can inhibit their ability to function properly and may lead to death.
6 NSF is a progressive disease for which there is no known cure.

7 23. NSF is a man-made disease. It only occurs in patients who have received a gadolinium-
8 based contrast agent.

9 24. Gadolinium is a highly toxic heavy metal. It does not occur naturally in the human
10 body. The only known route for gadolinium to enter the human body is injection of a gadolinium-
11 based contrast agent.

12 25. Because gadolinium is toxic, it has to be coated to keep it from coming in contact with
13 human tissue when injected. This coating process is called chelation.

14 26. Gadolinium is eliminated from the body by the kidneys. Gadolinium-based contrast
15 agents are not safe if the chelate separates from the gadolinium, which is what happens over time if
16 kidneys are not functioning properly. Individuals with impaired kidney function risk dechelation, and
17 cannot efficiently or quickly eliminate gadolinium from their bodies. Defendants never tested the
18 safety of their gadolinium-based contrast agents in individuals with kidney impairment.

19 27. On information and belief, the gadolinium-based contrast agents injected into Plaintiff
20 were manufactured by Defendants.

21 28. In pre-clinical studies during which gadolinium-based contrast agents were injected into
22 laboratory animals, consistent patterns of toxicity including nephrogenic fibrotic changes in the
23 kidneys and other body organs occurred.

24 29. During the years that Defendants have manufactured, marketed, distributed, sold, and
25 administered gadolinium-based contrast agents, there have been numerous case reports, studies,
26 assessments, papers, and other clinical data that have described and/or demonstrated NSF in
27 connection with the use of gadolinium-based contrast agents.

28 30. Plaintiff received MRIs and/or MRAs utilizing gadolinium-based contrast agents.

1 31. Plaintiff had impaired kidney function at the time she received her first injection of
2 gadolinium-based contrast agent and continued to have impaired kidney function at the time she
3 received each subsequent injection of gadolinium-based contrast agent.

4 32. During the time period when Plaintiff received injections of Defendants' gadolinium-
5 based contrast agents, Defendants knew or should have known that the use of gadolinium-based
6 contrast agents created a risk of serious bodily injury and death in patients with impaired kidney
7 function.

8 33. Defendants failed to warn Plaintiff and her healthcare providers about the serious health
9 risks associated with gadolinium-based contrast agents, and failed to disclose the fact that there were
10 safer alternatives.

11 34. As a direct and proximate result of receiving injections of gadolinium-based contrast
12 agents manufactured, marketed, distributed, and sold by Defendants, Plaintiff developed NSF.

13 35. Defendants have repeatedly and consistently failed to advise consumers and/or their
14 healthcare providers of the causal relationship between gadolinium-based contrast agents and NSF in
15 patients with kidney impairment. Defendants knew or should have known of the risk of NSF posed by
16 gadolinium-based contrast agents to individuals with impaired kidney function years before they
17 finally issued warnings.

18 36. It was not until September 2007 that Bayer, GE, Bracco, and Mallinckrodt finally sent
19 letters to healthcare providers warning them of the risk of NSF to kidney impaired individuals who
20 received MRIs using gadolinium-based contrast agents.

21 37. Had Plaintiff and/or her healthcare providers been warned about the risks associated
22 with gadolinium-based contrast agents, she would not have been administered gadolinium-based
23 contrast agents and would not have been afflicted with NSF.

24 38. As a direct and proximate result of Plaintiff being administered gadolinium-based
25 contrast agents, she has suffered severe physical injury and pain and suffering, including, but not
26 limited to, the effects of NSF. Plaintiff's physical injuries and pain and suffering will inevitably
27 worsen over time and will in all likelihood lead to death.

28 39. As a direct and proximate result of being administered gadolinium-based contrast

1 contrast agents were safe for use. Defendants failed to adequately test gadolinium-based contrast
2 agents with respect to their use by consumers with kidney impairment.

3 53. Had Defendants adequately tested the safety of gadolinium-based contrast agents for
4 use by consumers with kidney impairment and disclosed those results to the medical community or the
5 public, Plaintiff would not have been administered gadolinium-based contrast agents.

6 54. As a direct and proximate result of Defendants' failure to adequately test the safety of
7 gadolinium-based contrast agents and as a direct and proximate result of Plaintiff being administered
8 gadolinium-based contrast agents as manufactured, designed, sold, supplied, marketed, and introduced
9 into the stream of commerce by Defendants, Plaintiff has suffered physical injury, harm, damages, and
10 economic loss and will continue to suffer such harm, damages, and economic loss in the future.

11 FOURTH CAUSE OF ACTION

12 NEGLIGENCE

13 55. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

14 56. Defendants had a duty to exercise reasonable care in the design, formulation, testing,
15 manufacture, labeling, marketing, sale and/or distribution of gadolinium-based contrast agents and the
16 MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents.
17 In particular, they had a duty to assure that their products did not pose an unreasonable risk of bodily
18 harm and adverse events.

19 57. Defendants failed to exercise reasonable care in the design, formulation, manufacture,
20 sale, testing, marketing, or distribution of gadolinium-based contrast agents and the MRI and MRA
21 machines designed to be used in conjunction with gadolinium-based contrast agents in that they knew
22 or should have known that the products could cause significant bodily harm or death and were not safe
23 for use by certain types of consumers.

24 58. Defendants failed to exercise ordinary care in the labeling of gadolinium-based contrast
25 agents and the labeling of MRI and MRA machines designed to be used in conjunction with
26 gadolinium-based contrast agents and failed to issue to consumers and their health care providers
27 adequate warnings concerning the risks of serious bodily injury or death due to the use of gadolinium-
28 based contrast agents and the MRI and MRA machines designed to be used in conjunction with

1 gadolinium-based contrast agents.

2 59. Despite the fact that Defendants knew or should have known that gadolinium-based
3 contrast agents and the MRI and MRA machines designed to be used in conjunction with gadolinium-
4 based contrast agents posed a serious risk of bodily harm to consumers, Defendants unreasonably
5 continued to manufacture and market gadolinium-based contrast agents and the MRI and MRA
6 machines designed to be used in conjunction with gadolinium-based contrast agents for administration
7 to MRI and MRA patients with kidney impairment and failed to exercise reasonable care with respect
8 to post-sale warnings and instructions for safe use.

9 60. At all relevant times, it was foreseeable to Defendants that consumers like Plaintiff
10 would suffer injury as a result of their failure to exercise ordinary care as described above.

11 61. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered
12 physical injuries, harm, damages, and economic loss and will continue to suffer such harm, damages
13 and economic loss in the future.

14 62. The foregoing acts, conduct and omissions of Defendants were vile, base, willful,
15 malicious, wanton, oppressive, and fraudulent, and were done with a conscious disregard for the
16 health, safety, and rights of Plaintiffs and other users of Defendants' products, and for the primary
17 purpose of increasing Defendants' profits. As such, Plaintiffs are entitled to exemplary damages.

18 FIFTH CAUSE OF ACTION

19 NEGLIGENT MISREPRESENTATION

20 63. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

21 64. Defendants supplied the public and Plaintiff's healthcare providers with materially false
22 and incomplete information with respect to the safety of their gadolinium-based contrast agents.

23 65. The false information supplied by Defendants was that gadolinium-based contrast
24 agents were safe.

25 66. In supplying this false information, Defendants failed to exercise reasonable care.

26 67. The false information communicated by Defendants to Plaintiff and her healthcare
27 providers was material and Plaintiff justifiably relied in good faith on the information to her detriment.

28 68. As a direct and proximate result of Defendants' misrepresentations, Plaintiff was

1 administered gadolinium-based contrast agents and has suffered physical injury, harm, damages, and
2 economic loss and will continue to suffer such harm, damages, and economic loss in the future.

3 **SIXTH CAUSE OF ACTION**

4 **FRAUD**

5 69. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

6 70. Defendants knowingly and intentionally made materially false and misleading
7 representations to Plaintiff's healthcare providers and to the public, to the effect that gadolinium-based
8 contrast agents were safe for use and that their labeling, marketing, and promotional materials fully
9 described all known risks associated with their product.

10 71. Defendants' representations were in fact false. Gadolinium-based contrast agents are
11 not safe for use and Defendants' labeling, marketing, and promotional materials did not fully describe
12 all known risks of the products.

13 72. Defendants had actual knowledge that gadolinium-based contrast agents created an
14 unreasonable risk of serious bodily injury and death to consumers, especially patients with kidney
15 impairment.

16 73. Defendants knowingly and intentionally omitted this information from their labeling,
17 marketing, and promotional materials and instead, labeled, promoted, and marketed their products as
18 safe for use in order to increase and sustain sales.

19 74. When Defendants made representations that gadolinium-based contrast agents were
20 safe for use, they knowingly and intentionally concealed and withheld from Plaintiff, her healthcare
21 providers, and the public, the fact that their gadolinium-based contrast agents are not safe for use in
22 consumers with kidney impairment.

23 75. Defendants had a duty to disclose that gadolinium-based contrast agents are not safe for
24 use in patients with kidney impairment. Defendants had superior knowledge of these facts that were
25 material to Plaintiff and her healthcare providers' decisions to use gadolinium-based contrast agents.

26 76. Plaintiff and her healthcare providers reasonably and justifiably relied on the
27 Defendants' representations that gadolinium-based contrast agents were safe for human use and that
28 Defendants' labeling, marketing, and promotional materials fully described all known risks associated

1 with the products.

2 77. Plaintiff did not know and could not have learned of the facts that the Defendants
3 omitted and suppressed. The facts suppressed and concealed by the Defendants are material. Had
4 Plaintiff and her healthcare providers known that gadolinium-based contrast agents are not safe for use
5 in patients with renal insufficiency, Plaintiff would not have been injected with gadolinium-based
6 contrast agents.

7 78. As a direct and proximate result of Defendants' misrepresentations and concealment,
8 Plaintiff was administered gadolinium-based contrast agents and has suffered physical injury, harm,
9 damages and economic loss and will continue to suffer such harm, damages, and economic loss in the
10 future.

11 79. The foregoing acts, conduct, and omissions of Defendants were vile, base, willful,
12 malicious, wanton, oppressive, and fraudulent, and were done with a conscious disregard for the
13 health, safety, and rights of Plaintiff and other users of Defendants' products, and for the primary
14 purpose of increasing Defendants' profits. As such Plaintiffs are entitled to exemplary damages.

15 **SEVENTH CAUSE OF ACTION**

16 **FRAUD: CONCEALMENT, SUPPRESSION OR**

17 **OMISSION OF MATERIAL FACTS**

18 80. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

19 81. Defendants omitted, suppressed, or concealed material facts concerning the dangers and
20 risk associated with the use of their gadolinium-based contrast agents, including but not limited to the
21 risks to patients with kidney impairment of developing NSF, and the fact that safer alternatives were
22 available. Further, Defendants purposely downplayed and understated the serious nature of the risks
23 associated with use of their gadolinium-based contrast agents in order to increase and sustain sales.

24 82. As a direct and proximate result of Defendants' concealment of material facts, Plaintiff
25 was administered gadolinium-based contrast agents and has suffered physical injury, harm, damages,
26 and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

27 83. The foregoing acts, conduct, and omissions of Defendants were vile, base, willful,
28 malicious, wanton, oppressive, and fraudulent, and were done with a conscious disregard for the

1 health, safety, and rights of Plaintiff and other users of Defendants' products, and for the primary
2 purpose of increasing Defendants' profits. As such Plaintiffs are entitled to exemplary damages.

3 **EIGHTH CAUSE OF ACTION**

4 **BREACH OF EXPRESS WARRANTY**

5 84. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

6 85. Defendants expressly warranted that gadolinium-based contrast agents were safe and
7 effective.

8 86. The gadolinium-based contrast agents manufactured and sold by Defendants did not
9 conform to these express representations because they cause serious injury to consumers when
10 administered in recommended dosages.

11 87. As a direct and proximate result of Defendants' breach of warranty, Plaintiff has
12 suffered physical injury, harm, damages, and economic loss and will continue to suffer such harm,
13 damages, and economic loss in the future.

14 **NINTH CAUSE OF ACTION**

15 **BREACH OF IMPLIED WARRANTY**

16 88. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

17 89. At the time Defendants designed, manufactured, marketed, sold, and distributed
18 gadolinium-based contrast agents, Defendants knew of the use for which gadolinium-based contrast
19 agents was intended and impliedly warranted the product to be of merchantable quality and safe for
20 such use.

21 90. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether
22 gadolinium-based contrast agents were of merchantable quality and safe for their intended use and
23 upon Defendants' implied warranty as to such matters.

24 91. Contrary to such implied warranty, gadolinium-based contrast agents were not of
25 merchantable quality or safe for their intended use because the product was unreasonably dangerous as
26 described above.

27 92. As a direct and proximate result of Defendants' breach of warranty, Plaintiff has
28 suffered physical injury, harm, damages, and economic loss and will continue to suffer such harm,

1 damages, and economic loss in the future.

2 **TENTH CAUSE OF ACTION**

3 **VIOLATION OF GEORGIA CONSUMER PROTECTION STATUTES**

4 93. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

5 94. Defendants have engaged in unfair competition or unfair or deceptive acts or practices
6 in violation of Ga. Code Ann. §§ 10-1-372 and 10-1-420 including but not limited to the following:

7 a. Marketing, promoting or selling Magnevist, Omniscan, OptiMark, MultiHance, or
8 ProHance for use with MRAs and other off-label uses by impliedly representing that such products are
9 approved for use with MRAs and other off-label uses, when in fact there is no such approval;

10 b. Representing that gadolinium-based contrast agents are safe and effective for all
11 patients, including patients with kidney impairment, when in fact they are not;

12 c. Representing that MRIs and MRAs using gadolinium-based contrast agents are safer or
13 more effective than other imaging methods that do not require the use of gadolinium-based contrast
14 agents when in fact they are not;

15 d. Marketing, promoting, or selling their products as safer or superior to other brands of
16 gadolinium-based contrast agents;

17 e. Marketing, promoting or selling Magnevist, Omniscan, OptiMark, MultiHance, or
18 ProHance as inert or with words to that effect;

19 f. Marketing, promoting or selling Magnevist, Omniscan, OptiMark, MultiHance, or
20 ProHance for use with MRAs or other off-label uses by expressly or impliedly representing that they
21 are safe for such use; and

22 g. Remaining silent despite their knowledge of the growing body of evidence regarding
23 the danger of NSF and doing so because the prospect of huge profits outweighed health and safety
24 issues.

25 95. As a direct and proximate result of Defendants' unfair methods of competition and
26 unfair or deceptive actions or practices, Plaintiff was administered gadolinium-based contrast agents
27 and has suffered serious physician injury, harm, damages, and economic loss and will continue to
28 suffer such harm, damages, and economic loss in the future.

ELEVENTH CAUSE OF ACTION

LOSS OF CONSORTIUM

96. Plaintiff Michael Osborn ("Mr. Osborn") incorporates by reference and realleges each paragraph set forth above.

97. Michael Osborn is the husband of Amy Osborn.

98. As a direct and proximate result of Defendants conducts, Mr. Osborn has been deprived of his wife's love, society, companionship, and services and has otherwise suffered loss, the extent of which will be more fully adduced at the trial of this matter.

WHEREFORE, Plaintiffs pray for relief as follows:

1. Compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, loss of consortium, and other non-economic damages in an amount to be determined at trial of this action;
2. Past and future medical expenses, income, and other economic damages in an amount to be determined at trial of this action;
3. Punitive damages in an amount to be determined at trial of this action;
4. Pre- and post-judgment interest;
5. Attorneys' fees, expenses, and costs; and
6. Such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury.

Respectfully submitted this 7th day of March, 2008.

LEVIN SIMES KAISER & GORNICK LLP

By:

Debra DeCarli
Debra DeCarli, Esq.

EXHIBIT “C”

EGN

RECEIVED
08 MAY -5 PM 5:17
U.S. DISTRICT COURT
SAN FRANCISCO, CALIFORNIA

1 Lawrence J. Gornick (SBN 136290)
2 Debra DeCarli (SBN 237642)
3 **LEVIN SIMES KAISER & GORNICK LLP**
4 44 Montgomery Street, 36th Floor
5 San Francisco, CA 94104
6 Telephone: (415) 646-7160
7 Fax: (415) 981-1270
8 lgornick@lskg-law.com
9 ddecarli@lskg-law.com

E-filing

Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

WILLIAM PASCHAL and PATRICIA
PASCHAL,

Plaintiffs,

vs.

BAYER HEALTHCARE
PHARMACEUTICALS, INC.; BAYER
HEALTHCARE LLC; GENERAL ELECTRIC
COMPANY; GE HEALTHCARE, INC.;
COVIDIEN, INC.; MALLINCKRODT, INC.;
and BRACCO DIAGNOSTICS, INC.

Defendants.

Case No:

EMC

1298

ORIGINAL COMPLAINT

DEMAND FOR JURY TRIAL

Plaintiffs, William Paschal and Patricia Paschal, (hereinafter "Plaintiffs") allege as follows:

NATURE OF THE CASE

1. Plaintiff William Paschal ("Mr. Paschal" or "Plaintiff") has nephrogenic systemic fibrosis ("NSF"). NSF is an incurable, painful, and deadly disease. Mr. Paschal contracted NSF as a result of receiving intravenous injections of gadolinium-based contrast agents manufactured by the Defendants. Gadolinium-based contrast agents are not safe for use in individuals such as Plaintiff who have impaired kidney function. Defendants represented that the gadolinium-based contrast agents were safe and failed to warn of the risks associated with gadolinium-based contrast agents.

JURISDICTION AND VENUE

2. This Court has jurisdiction pursuant to 28 USC § 1332. Plaintiffs are citizens of a state that is different from the states where Defendants are incorporated and have their respective principal

1 places of business. The amount in controversy for this case exceeds \$75,000. Venue pursuant to
 2 28 USC § 1391(c) is proper because Defendants have sufficient contacts within the City and County of
 3 San Francisco, California to subject each of them to personal jurisdiction.

4 INTRADISTRICT ASSIGNMENT

5 3. On information and belief, a substantial part of the events or omissions which give rise
 6 to the claim occurred in the County and City of San Francisco.

7 PARTIES

8 *Plaintiffs*

9 4. William Paschal and his wife Patricia Paschal are residents of the State of
 10 Massachusetts.

11 *Defendants*

12 5. Defendants Bayer HealthCare Pharmaceuticals, Inc. and Bayer Healthcare LLC (jointly
 13 referred to as "Bayer") manufacture, market, and sell Magnevist, a gadolinium-based contrast agent
 14 that, on information and belief, was injected into Plaintiff.

15 6. Defendant Bayer HealthCare LLC is a Delaware business entity with its principal place
 16 of business in New York.

17 7. Defendant Bayer HealthCare Pharmaceuticals, Inc. is a Delaware business entity with
 18 its principal place of business in New Jersey. Defendant Bayer HealthCare Pharmaceuticals, Inc. is
 19 the U.S.-based pharmaceuticals unit of Bayer Healthcare LLC.

20 8. At all times relevant to this complaint, Bayer was in the business of designing,
 21 licensing, manufacturing, distributing, selling, marketing, promoting, and introducing Magnevist into
 22 interstate commerce.

23 9. Defendants General Electric Company and GE Healthcare, Inc. (jointly referred to as
 24 "GE") manufacture, market, and sell Omniscan, a gadolinium-based contrast agent that, on
 25 information and belief, was injected into Plaintiff.

26 10. Defendant General Electric Company is a New York business entity with its principal
 27 place of business in Connecticut.

28 11. Defendant GE Healthcare, Inc. is a Delaware corporation with its principal place of

1 business in New Jersey.

2 12. At all times relevant to this complaint, GE was in the business of designing, licensing,
3 manufacturing, distributing, selling, marketing, promoting, and introducing Omniscan into interstate
4 commerce.

5 13. Defendants Covidien Inc. and Mallinckrodt, Inc. (collectively referred to as
6 "Covidien") manufacture, market, and sell OptiMARK, a gadolinium-based contrast agent that, on
7 information and belief, was injected into Plaintiff.

8 14. Defendant Covidien, Inc. is a Delaware corporation with its principal place of business
9 in New Hampshire.

10 15. Defendant Mallinckrodt, Inc. is a Delaware corporation with its principal place of
11 business in Missouri. Mallinckrodt is a business unit of Covidien, Inc.

12 16. At all times relevant to this complaint, Covidien was in the business of designing,
13 licensing, manufacturing, distributing, selling, marketing, promoting, and introducing OptiMARK into
14 interstate commerce.

15 17. Defendant Bracco Diagnostics, Inc. ("Bracco") manufactures, markets, and sells
16 MultiHance and ProHance, gadolinium-based contrast agents that, on information and belief, were
17 injected into Plaintiff.

18 18. Bracco Diagnostics, Inc. is a Delaware corporation with its principal place of business
19 in New Jersey.

20 19. At all times relevant to this complaint, Bracco was in the business of designing,
21 licensing, manufacturing, distributing, selling, marketing, promoting, and introducing MultiHance and
22 ProHance into interstate commerce.

23 20. The Bayer, GE, Covidien, and Bracco Defendants are collectively referred to as
24 Defendants.

25 FACTS

26 21. Mr. Paschal was diagnosed with NSF in or around January 2008.

27 22. NSF is predominantly characterized by discoloration, thickening, tightening, and
28 swelling of the skin after receiving a gadolinium-based contrast agent injection. These fibrotic and

1 edematous changes produce muscular weakness and inhibit flexion and extension of joints, resulting in
2 contractures. NSF often progresses to painful inhibition of the ability to use the arms, legs, hands,
3 feet, and other joints. The skin changes that begin as darkened patches or plaques progress to a
4 "woody" texture and are accompanied by burning, itching, or severe pain in the areas of involvement.
5 NSF also progresses to a fibrotic or scarring condition of other body organs such as the lungs, heart,
6 liver, and musculature, and that can inhibit their ability to function properly and may lead to death.
7 NSF is a progressive disease for which there is no known cure.

8 23. NSF is a man-made disease. It only occurs in patients who have received a gadolinium-
9 based contrast agent.

10 24. Gadolinium is a highly toxic heavy metal. It does not occur naturally in the human
11 body. The only known route for gadolinium to enter the human body is injection of a gadolinium-
12 based contrast agent.

13 25. Because gadolinium is toxic, it has to be coated to keep it from coming in contact with
14 human tissue when injected. This coating process is called chelation.

15 26. Gadolinium is eliminated from the body by the kidneys. Gadolinium-based contrast
16 agents are not safe if the chelate separates from the gadolinium, which is what happens over time if
17 kidneys are not functioning properly. Individuals with impaired kidney function risk dechelation, and
18 cannot efficiently or quickly eliminate gadolinium from their bodies. Defendants never tested the
19 safety of their gadolinium-based contrast agents in individuals with kidney impairment.

20 27. On information and belief, the gadolinium-based contrast agents injected into Plaintiff
21 were manufactured by Defendants.

22 28. In pre-clinical studies during which gadolinium-based contrast agents were injected into
23 laboratory animals, consistent patterns of toxicity including nephrogenic fibrotic changes in the
24 kidneys and other body organs occurred.

25 29. During the years that Defendants have manufactured, marketed, distributed, sold, and
26 administered gadolinium-based contrast agents, there have been numerous case reports, studies,
27 assessments, papers, and other clinical data that have described and/or demonstrated NSF in
28 connection with the use of gadolinium-based contrast agents.

1 30. Plaintiff received MRIs and/or MRAs utilizing gadolinium-based contrast agents.

2 31. Plaintiff had impaired kidney function at the time he received his first injection of
3 gadolinium-based contrast agent and continued to have impaired kidney function at the time he
4 received each subsequent injection of gadolinium-based contrast agent.

5 32. During the time period when Plaintiff received injections of Defendants' gadolinium-
6 based contrast agents, Defendants knew or should have known that the use of gadolinium-based
7 contrast agents created a risk of serious bodily injury and death in patients with impaired kidney
8 function.

9 33. Defendants failed to warn Plaintiff and his healthcare providers about the serious health
10 risks associated with gadolinium-based contrast agents, and failed to disclose the fact that there were
11 safer alternatives.

12 34. As a direct and proximate result of receiving injections of gadolinium-based contrast
13 agents manufactured, marketed, distributed, and sold by Defendants, Plaintiff developed NSF.

14 35. Defendants have repeatedly and consistently failed to advise consumers and/or their
15 healthcare providers of the causal relationship between gadolinium-based contrast agents and NSF in
16 patients with kidney impairment. Defendants knew or should have known of the risk of NSF posed by
17 gadolinium-based contrast agents to individuals with impaired kidney function years before they
18 finally issued warnings.

19 36. It was not until September 2007 that Bayer, GE, Bracco, and Mallinckrodt finally sent
20 letters to healthcare providers warning them of the risk of NSF to kidney impaired individuals who
21 received MRIs using gadolinium-based contrast agents.

22 37. Had Plaintiff and/or his healthcare providers been warned about the risks associated
23 with gadolinium-based contrast agents, he would not have been administered gadolinium-based
24 contrast agents and would not have been afflicted with NSF.

25 38. As a direct and proximate result of Plaintiff being administered gadolinium-based
26 contrast agents, he has suffered severe physical injury and pain and suffering, including, but not
27 limited to, the effects of NSF. Plaintiff's physical injuries and pain and suffering will inevitably
28 worsen over time and will in all likelihood lead to death.

39. As a direct and proximate result of being administered gadolinium-based contrast agents, Plaintiffs suffered and continue to suffer significant mental anguish and emotional distress and will continue to suffer significant mental anguish and emotional distress in the future.

40. As a direct and proximate result of being administered gadolinium-based contrast agents, Plaintiffs have also incurred medical expenses and other economic damages and will continue to incur such expenses in the future.

DISCOVERY RULE & FRAUDULENT CONCEALMENT

41. The discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew or through the exercise of reasonable care and diligence should have known of the existence of their claims against all Defendants. The nature of Plaintiffs' injuries and damages, and their relationship to gadolinium-based contrast agents used in conjunction with MRIs and MRAs, was not discovered, and through reasonable care and due diligence could not have been discovered, by Plaintiffs, until a time less than two years before the filing of this Complaint. Therefore, under appropriate application of the discovery rule, Plaintiffs' suit was filed well within the applicable statutory limitations period.

42. Defendants are estopped from asserting a statute of limitations defense because all Defendants fraudulently concealed from Plaintiffs the nature of Plaintiffs' injury and the connection between the injury and all Defendants' tortious conduct.

FIRST CAUSE OF ACTION

STRICT LIABILITY: FAILURE TO WARN

43. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

44. Defendants' gadolinium-based contrast agents, and MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents, were defective due to inadequate warnings or instruction for use, both prior to marketing and post-marketing. Defendants knew or should have known that their products created significant risks of serious bodily harm and death to consumers. Defendants failed to adequately warn consumers and their healthcare providers of such risks.

45. Because of Defendants' failure to provide adequate warnings with their products, Plaintiff was injected with gadolinium-based contrast agents that the Defendants manufactured, designed, sold, supplied, marketed or otherwise introduced into the stream of commerce. Those gadolinium-based contrast agents are the legal cause of Plaintiff's physical injuries, harm, damages, and economic loss. Plaintiffs will continue to suffer such harm, damages, and economic loss in the future.

SECOND CAUSE OF ACTION

STRICT LIABILITY: DESIGN DEFECT

46. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

47. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of gadolinium-based contrast agents, and MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents.

48. The gadolinium-based contrast agents manufactured and supplied by Defendants were defective in design or formulation in that, when they left the hands of the Defendants, the foreseeable risks of the products exceeded the benefits associated with their design or formulation, or were more dangerous than an ordinary consumer would expect.

49. The foreseeable risks associated with the design or formulation of gadolinium-based contrast agents, and MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents, include, but are not limited to, the fact that the design or formulation of gadolinium-based contrast agents are more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

50. As a direct and proximate result of Plaintiff being administered gadolinium-based contrast agents as manufactured, designed, sold, supplied, marketed, and introduced into the stream of commerce by Defendants, Plaintiff has suffered physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

THIRD CAUSE OF ACTION

STRICT LIABILITY: FAILURE TO ADEQUATELY TEST

51. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

1 52. Defendants advised consumers and the medical community that gadolinium-based
2 contrast agents were safe for use. Defendants failed to adequately test gadolinium-based contrast
3 agents with respect to their use by consumers with kidney impairment.

4 53. Had Defendants adequately tested the safety of gadolinium-based contrast agents for
5 use by consumers with kidney impairment and disclosed those results to the medical community or the
6 public, Plaintiff would not have been administered gadolinium-based contrast agents.

7 54. As a direct and proximate result of Defendants' failure to adequately test the safety of
8 gadolinium-based contrast agents and as a direct and proximate result of Plaintiff being administered
9 gadolinium-based contrast agents as manufactured, designed, sold, supplied, marketed, and introduced
10 into the stream of commerce by Defendants, Plaintiff has suffered physical injury, harm, damages, and
11 economic loss and will continue to suffer such harm, damages, and economic loss in the future.

12 **FOURTH CAUSE OF ACTION**

13 **NEGLIGENCE**

14 55. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

15 56. Defendants had a duty to exercise reasonable care in the design, formulation, testing,
16 manufacture, labeling, marketing, sale and/or distribution of gadolinium-based contrast agents and the
17 MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents.
18 In particular, they had a duty to assure that their products did not pose an unreasonable risk of bodily
19 harm and adverse events.

20 57. Defendants failed to exercise reasonable care in the design, formulation, manufacture,
21 sale, testing, marketing, or distribution of gadolinium-based contrast agents and the MRI and MRA
22 machines designed to be used in conjunction with gadolinium-based contrast agents in that they knew
23 or should have known that the products could cause significant bodily harm or death and were not safe
24 for use by certain types of consumers.

25 58. Defendants failed to exercise ordinary care in the labeling of gadolinium-based contrast
26 agents and the labeling of MRI and MRA machines designed to be used in conjunction with
27 gadolinium-based contrast agents and failed to issue to consumers and their health care providers
28 adequate warnings concerning the risks of serious bodily injury or death due to the use of gadolinium-

1 based contrast agents and the MRI and MRA machines designed to be used in conjunction with
2 gadolinium-based contrast agents.

3 59. Despite the fact that Defendants knew or should have known that gadolinium-based
4 contrast agents and the MRI and MRA machines designed to be used in conjunction with gadolinium-
5 based contrast agents posed a serious risk of bodily harm to consumers, Defendants unreasonably
6 continued to manufacture and market gadolinium-based contrast agents and the MRI and MRA
7 machines designed to be used in conjunction with gadolinium-based contrast agents for administration
8 to MRI and MRA patients with kidney impairment and failed to exercise reasonable care with respect
9 to post-sale warnings and instructions for safe use.

10 60. At all relevant times, it was foreseeable to Defendants that consumers like Plaintiff
11 would suffer injury as a result of their failure to exercise ordinary care as described above.

12 61. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered
13 physical injuries, harm, damages, and economic loss and will continue to suffer such harm, damages
14 and economic loss in the future.

15 62. The foregoing acts, conduct and omissions of Defendants were vile, base, willful,
16 malicious, wanton, oppressive, and fraudulent, and were done with a conscious disregard for the
17 health, safety, and rights of Plaintiffs and other users of Defendants' products, and for the primary
18 purpose of increasing Defendants' profits. As such, Plaintiffs are entitled to exemplary damages.

19 **FIFTH CAUSE OF ACTION**

20 **NEGLIGENT MISREPRESENTATION**

21 63. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

22 64. Defendants supplied the public and Plaintiff's healthcare providers with materially false
23 and incomplete information with respect to the safety of their gadolinium-based contrast agents.

24 65. The false information supplied by Defendants was that gadolinium-based contrast
25 agents were safe.

26 66. In supplying this false information, Defendants failed to exercise reasonable care.

27 67. The false information communicated by Defendants to Plaintiff and his healthcare
28 providers was material and Plaintiff justifiably relied in good faith on the information to his detriment.

68. As a direct and proximate result of Defendants' misrepresentations, Plaintiff was administered gadolinium-based contrast agents and has suffered physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

SIXTH CAUSE OF ACTION

FRAUD

69. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

70. Defendants knowingly and intentionally made materially false and misleading representations to Plaintiff's healthcare providers and to the public, to the effect that gadolinium-based contrast agents were safe for use and that their labeling, marketing, and promotional materials fully described all known risks associated with their product.

71. Defendants' representations were in fact false. Gadolinium-based contrast agents are not safe for use and Defendants' labeling, marketing, and promotional materials did not fully describe all known risks of the products.

72. Defendants had actual knowledge that gadolinium-based contrast agents created an unreasonable risk of serious bodily injury and death to consumers, especially patients with kidney impairment.

73. Defendants knowingly and intentionally omitted this information from their labeling, marketing, and promotional materials and instead, labeled, promoted, and marketed their products as safe for use in order to increase and sustain sales.

74. When Defendants made representations that gadolinium-based contrast agents were safe for use, they knowingly and intentionally concealed and withheld from Plaintiff, his healthcare providers, and the public, the fact that their gadolinium-based contrast agents are not safe for use in consumers with kidney impairment.

75. Defendants had a duty to disclose that gadolinium-based contrast agents are not safe for use in patients with kidney impairment. Defendants had superior knowledge of these facts that were material to Plaintiff and his healthcare providers' decisions to use gadolinium-based contrast agents.

76. Plaintiff and his healthcare providers reasonably and justifiably relied on the Defendants' representations that gadolinium-based contrast agents were safe for human use and that

1 Defendants' labeling, marketing, and promotional materials fully described all known risks associated
2 with the products.

3 77. Plaintiff did not know and could not have learned of the facts that the Defendants
4 omitted and suppressed. The facts suppressed and concealed by the Defendants are material. Had
5 Plaintiff and his healthcare providers known that gadolinium-based contrast agents are not safe for use
6 in patients with renal insufficiency, Plaintiff would not have been injected with gadolinium-based
7 contrast agents.

8 78. As a direct and proximate result of Defendants' misrepresentations and concealment,
9 Plaintiff was administered gadolinium-based contrast agents and has suffered physical injury, harm,
10 damages and economic loss and will continue to suffer such harm, damages, and economic loss in the
11 future.

12 79. The foregoing acts, conduct, and omissions of Defendants were vile, base, willful,
13 malicious, wanton, oppressive, and fraudulent, and were done with a conscious disregard for the
14 health, safety, and rights of Plaintiff and other users of Defendants' products, and for the primary
15 purpose of increasing Defendants' profits. As such Plaintiffs are entitled to exemplary damages.

16 **SEVENTH CAUSE OF ACTION**

17 **FRAUD: CONCEALMENT, SUPPRESSION OR**

18 **OMISSION OF MATERIAL FACTS**

19 80. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

20 81. Defendants omitted, suppressed, or concealed material facts concerning the dangers and
21 risk associated with the use of their gadolinium-based contrast agents, including but not limited to the
22 risks to patients with kidney impairment of developing NSF, and the fact that safer alternatives were
23 available. Further, Defendants purposely downplayed and understated the serious nature of the risks
24 associated with use of their gadolinium-based contrast agents in order to increase and sustain sales,

25 82. As a direct and proximate result of Defendants' concealment of material facts, Plaintiff
26 was administered gadolinium-based contrast agents and has suffered physical injury, harm, damages,
27 and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

28 83. The foregoing acts, conduct, and omissions of Defendants were vile, base, willful,

1 malicious, wanton, oppressive, and fraudulent, and were done with a conscious disregard for the
2 health, safety, and rights of Plaintiff and other users of Defendants' products, and for the primary
3 purpose of increasing Defendants' profits. As such Plaintiffs are entitled to exemplary damages.

4 **EIGHTH CAUSE OF ACTION**

5 **BREACH OF EXPRESS WARRANTY**

6 84. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

7 85. Defendants expressly warranted that gadolinium-based contrast agents were safe and
8 effective.

9 86. The gadolinium-based contrast agents manufactured and sold by Defendants did not
10 conform to these express representations because they cause serious injury to consumers when
11 administered in recommended dosages.

12 87. As a direct and proximate result of Defendants' breach of warranty, Plaintiff has
13 suffered physical injury, harm, damages, and economic loss and will continue to suffer such harm,
14 damages, and economic loss in the future.

15 **NINTH CAUSE OF ACTION**

16 **BREACH OF IMPLIED WARRANTY**

17 88. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

18 89. At the time Defendants designed, manufactured, marketed, sold, and distributed
19 gadolinium-based contrast agents, Defendants knew of the use for which gadolinium-based contrast
20 agents was intended and impliedly warranted the product to be of merchantable quality and safe for
21 such use.

22 90. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether
23 gadolinium-based contrast agents were of merchantable quality and safe for their intended use and
24 upon Defendants' implied warranty as to such matters.

25 91. Contrary to such implied warranty, gadolinium-based contrast agents were not of
26 merchantable quality or safe for their intended use because the product was unreasonably dangerous as
27 described above.

28 92. As a direct and proximate result of Defendants' breach of warranty, Plaintiff has

1 suffered physical injury, harm, damages, and economic loss and will continue to suffer such harm,
2 damages, and economic loss in the future.

3 **TENTH CAUSE OF ACTION**

4 **LOSS OF CONSORTIUM**

5 93. Plaintiff Patricia Paschal ("Mrs. Paschal") incorporates by reference and realleges each
6 paragraph set forth above.

7 94. Patricia Paschal is the wife of William Paschal.

8 95. As a direct and proximate result of Defendants conducts, Mrs. Paschal has been
9 deprived of her husband's love, society, companionship, and services and has otherwise suffered loss,
10 the extent of which will be more fully adduced at the trial of this matter.

11 WHEREFORE, Plaintiffs pray for relief as follows:

- 12 1. Compensatory damages in excess of the jurisdictional amount, including, but not limited to
13 pain, suffering, emotional distress, loss of enjoyment of life, loss of consortium, and other
14 non-economic damages in an amount to be determined at trial of this action;
15 2. Past and future medical expenses, income, and other economic damages in an amount to be
16 determined at trial of this action;
17 3. Punitive damages in an amount to be determined at trial of this action;
18 4. Pre- and post-judgment interest;
19 5. Attorneys' fees, expenses, and costs; and
20 6. Such further relief as this Court deems necessary, just, and proper.

21 **DEMAND FOR JURY TRIAL**

22 Plaintiffs hereby demand a trial by jury.

23 Respectfully submitted this 5th day of March, 2008.

24 LEVIN SIMES KAISER & GORNICK LLP

25 By: Debra DeCarli
26 Debra DeCarli, Esq.

JS 44 (Rev. 12/07) (and rev 1-16-08)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON PAGE TWO OF THE FORM.)

I (a) PLAINTIFFS

WILLIAM PASCHAL and PATRICIA PASCHAL

DEFENDANTS

SEE ATTACHED LIST

(b) County of Residence of First Listed Plaintiff: Hampshire County, MA
(EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

(c) Attorney's (Firm Name, Address, and Telephone Number)

Lawrence J. Gornick and Debra DeCarli 415-646-7160
Levin Shinn Kaiser & Gornick LLP
44 Montgomery Street, Suite 3600
San Francisco CA 94104

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff ☐ 3 Federal Question (U.S. Government Not a Party)
☐ 2 U.S. Government Defendant ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- (For Diversity Cases Only)
- | | | | | | |
|---|---------------------------------------|------------------------------|---|----------------------------|---------------------------------------|
| Citizen of This State | <input type="checkbox"/> 1 | <input type="checkbox"/> DEF | Incorporated or Principal Place of Business in This State | <input type="checkbox"/> 4 | <input type="checkbox"/> DEF |
| Citizen of Another State | <input checked="" type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business in Another State | <input type="checkbox"/> 5 | <input checked="" type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS	PERFECTION/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance	<input type="checkbox"/> 310 Airplane	<input type="checkbox"/> 610 Aggravation	<input type="checkbox"/> 422 Appeal 28 USC 151	<input type="checkbox"/> 400 State Reapportionment
<input type="checkbox"/> 120 Marine	<input type="checkbox"/> 315 Airplane Product Liability	<input type="checkbox"/> 620 Other Food & Drug	<input type="checkbox"/> 423 Withdrawal 28 USC 157	<input type="checkbox"/> 410 Antitrust
<input type="checkbox"/> 130 Miller Act	<input type="checkbox"/> 320 Assault, Libel & Slander	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881	<input type="checkbox"/> 430 Commerce	<input type="checkbox"/> 420 Banks and Banking
<input type="checkbox"/> 140 Negotiable Instrument	<input type="checkbox"/> 330 Federal Employers' Liability	<input type="checkbox"/> 630 Liquor Laws	<input type="checkbox"/> 440 Deposition	<input type="checkbox"/> 430 Consumer
<input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment	<input type="checkbox"/> 340 Marine	<input type="checkbox"/> 640 R.R. & Truck	<input type="checkbox"/> 450 Copyright	<input type="checkbox"/> 470 Racketeer Influence and Corrupt Organizations
<input type="checkbox"/> 151 Mediation Act	<input type="checkbox"/> 345 Marine Product Liability	<input type="checkbox"/> 650 Airline Regs.	<input type="checkbox"/> 460 Patent	<input type="checkbox"/> 480 Consumer Credit
<input type="checkbox"/> 152 Recovery of Defuncted Student Loans (Both Veterans)	<input type="checkbox"/> 350 Motor Vehicle	<input type="checkbox"/> 660 Occupational Safety/Health	<input type="checkbox"/> 470 Trademark	<input type="checkbox"/> 490 Cable/Sat. TV
<input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits	<input type="checkbox"/> 355 Motor Vehicle Product Liability	<input type="checkbox"/> 690 Other	<input type="checkbox"/> 480 Social Security	<input type="checkbox"/> 510 Selective Service
<input type="checkbox"/> 160 Stockholders' Suits	<input type="checkbox"/> 360 Other Personal Injury	<input type="checkbox"/> 700 Labor	<input type="checkbox"/> 490 Social Security Exchange	<input type="checkbox"/> 520 Securities/Commodities
<input type="checkbox"/> 170 Other Contract	<input type="checkbox"/> 370 Truth in Lending	<input type="checkbox"/> 710 Poly Labor Standards Act	<input type="checkbox"/> 500 Social Security	<input type="checkbox"/> 530 Customer Challenge 12 USC 3410
<input type="checkbox"/> 180 Contract Product Liability	<input type="checkbox"/> 380 Other Personal Property Damage	<input type="checkbox"/> 720 Labor/Mgmt. Relations	<input type="checkbox"/> 510 HIA (13950)	<input type="checkbox"/> 540 Other Statutory Actions
<input type="checkbox"/> 190 Franchise	<input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosures Act	<input type="checkbox"/> 520 Black Lung (923)	<input type="checkbox"/> 550 Agricultural Act
		<input type="checkbox"/> 740 Railway Labor Act	<input type="checkbox"/> 530 DFWC/DWW (405(a))	<input type="checkbox"/> 560 Economic Stabilization Act
		<input type="checkbox"/> 750 Other Labor Legislation	<input type="checkbox"/> 540 SSID Title XVI	<input type="checkbox"/> 570 Environmental Matters
		<input type="checkbox"/> 760 Equal Pay Act	<input type="checkbox"/> 550 RSI (405(a))	<input type="checkbox"/> 580 Energy Allocation Act
		<input type="checkbox"/> 770 Equal Pay Act		<input type="checkbox"/> 590 Freedom of Information Act
		<input type="checkbox"/> 780 Equal Pay Act		<input type="checkbox"/> 600 Appeal of Fee Determination Under Equal Access to Justice
		<input type="checkbox"/> 790 Equal Pay Act		<input type="checkbox"/> 610 Constitutionality of State Statutes
		<input type="checkbox"/> 800 Equal Pay Act		
		<input type="checkbox"/> 810 Equal Pay Act		
		<input type="checkbox"/> 820 Equal Pay Act		
		<input type="checkbox"/> 830 Equal Pay Act		
		<input type="checkbox"/> 840 Equal Pay Act		
		<input type="checkbox"/> 850 Equal Pay Act		
		<input type="checkbox"/> 860 Equal Pay Act		
		<input type="checkbox"/> 870 Equal Pay Act		
		<input type="checkbox"/> 880 Equal Pay Act		
		<input type="checkbox"/> 890 Equal Pay Act		
		<input type="checkbox"/> 900 Equal Pay Act		
		<input type="checkbox"/> 910 Equal Pay Act		
		<input type="checkbox"/> 920 Equal Pay Act		
		<input type="checkbox"/> 930 Equal Pay Act		
		<input type="checkbox"/> 940 Equal Pay Act		
		<input type="checkbox"/> 950 Equal Pay Act		
		<input type="checkbox"/> 960 Equal Pay Act		
		<input type="checkbox"/> 970 Equal Pay Act		
		<input type="checkbox"/> 980 Equal Pay Act		
		<input type="checkbox"/> 990 Equal Pay Act		

V. ORIGIN (Place an "X" in One Box Only)

- ☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing. (Do not cite jurisdictional statutes unless diversity):

28 USC 1332

Brief description of cause:
Product Liability

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

CHECK YES only if demanded in complaint:
JURY DEMAND: ☐ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

PLEASE REFER TO CIVIL L.R. 3-12 CONCERNING REQUIREMENT TO FILE "NOTICE OF RELATED CASE". MDL 1909 (pending)

IX. DIVISIONAL ASSIGNMENT (CIVIL L.R. 3-2)

(PLACE AND "X" IN ONE BOX ONLY)

☒ SAN FRANCISCO/OAKLAND

☐ SAN JOSE

DATE

March 5, 2008

SIGNATURE OF ATTORNEY OR RECORDS

Debra DeCarli

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

Paschal, et al. v Bayer Healthcare Pharmaceuticals Corp, et al.

ATTACHED DEFENDANT LIST FOR CIVIL COVER SHEET

BAYER HEALTHCARE PHARMACEUTICALS, INC.

BAYER HEALTHCARE LLC

GENERAL ELECTRIC COMPANY

GE HEALTHCARE, INC.

COVIDIEN, INC.

MALLINCKRODT, INC.

BRACCO DIAGNOSTICS, INC.

E-filing

EMC

CV 08 1298

U.S. District Court Northern California

ECF Registration Information Handout

The case you are participating in has been designated for this court's Electronic Case Filing (ECF) Program, pursuant to Civil Local Rule 5-4 and General Order 45. This means that you must (check off the boxes ☒ when done):

- ☐ 1) Serve this ECF Registration Information Handout on all parties in the case along with the complaint, or for removals, the removal notice. DO NOT serve the efile application form, just this handout.

Each attorney representing a party must also:

- ☐ 2) Register to become an efiler by filling out the efiler application form. Follow ALL the instructions on the form carefully. If you are already registered in this district, do not register again, your registration is valid for life on all ECF cases in this district.
- ☐ 3) Email (do not efile) the complaint and, for removals, the removal notice and all attachments, in PDF format within ten business days, following the instructions below. You do not need to wait for your registration to be completed to email the court.
- ☐ 4) Access dockets and documents using PACER (Public Access to Court Electronic Records). If your firm already has a PACER account, please use that - it is not necessary to have an individual account. PACER registration is free. If you need to establish or check on an account, visit: <http://pacer.psc.uscourts.gov> or call (800) 676-6856.

BY SIGNING AND SUBMITTING TO THE COURT A REQUEST FOR AN ECF USER ID AND PASSWORD, YOU CONSENT TO ENTRY OF YOUR E-MAIL ADDRESS INTO THE COURT'S ELECTRONIC SERVICE REGISTRY FOR ELECTRONIC SERVICE ON YOU OF ALL E-FILED PAPERS, PURSUANT TO RULES 77 and 5(b)(2)(D) (eff. 12.1.01) OF THE FEDERAL RULES OF CIVIL PROCEDURE.

All subsequent papers submitted by attorneys in this case shall be filed electronically. Unrepresented litigants must file and serve in paper form, unless prior leave to file electronically is obtained from the assigned judge.

ECF registration forms, interactive tutorials and complete instructions for efilng may be found on the ECF website: <http://ecf.cand.uscourts.gov>

Submitting Initiating Documents

PDF versions of all the initiating documents originally submitted to the court - (Complaint or Notice of Removal, exhibits, etc.) must be emailed (not efiled) to the PDF email box for the presiding judge (not the referring judge, if there is one) within 10 (ten) business days of the opening of your case. For a complete list of the email addresses, please go to: <http://ecf.cand.uscourts.gov> and click on [Judges].

You must include the case number and judge's initials in the subject line of all relevant emails to the court. You do not need to wait for your registration to email these documents.

These documents must be emailed instead of e-filed to prevent duplicate entries in the ECF system. All other documents must be e-filed from then on. You do not need to efile or email the Civil Cover Sheet, Summons, or any documents issued by the court at case opening; note that you do need to efile the Summons Returned.

Converting Documents to PDF

Conversion of a word processing document to a PDF file is required before any documents may be submitted to the Court's electronic filing system. Instructions for creating PDF files can be found at the ECF web site: <http://ecf.cand.uscourts.gov>, and click on [FAQ].

Email Guidelines: When sending an email to the court, the subject line of the email must contain the case number, judge's initials and the type of document(s) you are sending, and/or the topic of the email.

Examples: The examples below assume your case number is 03-09999 before the Honorable Charles R. Breyer:

Type of Document	Email Subject Line Text
Complaint Only	03-09999 CRB Complaint
Complaint and Notice of Related Case	03-09999 CRB Complaint, Related Case
Complaint and Motion for Temporary Restraining Order	03-09999 CRB Complaint, TRO

Questions

Almost all questions can be answered in our FAQs at <http://ecf.cand.uscourts.gov>, please check them first.

You may also email the ECF Help Desk at ECFhelpdesk@cand.uscourts.gov or call the toll-free ECF Help Desk number at: (866) 638-7829.

The ECF Help Desk is staffed Mondays through Fridays from 9:00am to 4:00pm Pacific time, excluding court holidays.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

E-filing

WILLIAM PASCHAL,

Plaintiff (s),

v.

BAYER HEALTHCARE,
Defendant(s).

No. C 08-01298 EMC

ORDER SETTING INITIAL CASE
MANAGEMENT CONFERENCE
AND ADR DEADLINES

IT IS HEREBY ORDERED that this action is assigned to the Honorable Edward M. Chen. When serving the complaint or notice of removal, the plaintiff or removing defendant must serve on all other parties a copy of this order, the Notice of Assignment of Case to a United States Magistrate Judge for Trial, and all other documents specified in Civil Local Rule 4-2. Counsel must comply with the case schedule listed below unless the Court otherwise orders.

IT IS FURTHER ORDERED that this action is assigned to the Alternative Dispute Resolution (ADR) Multi-Option Program governed by ADR Local Rule 3. Counsel and clients shall familiarize themselves with that rule and with the material entitled "Dispute Resolution Procedures in the Northern District of California" on the Court ADR Internet site at www.adr.cand.uscourts.gov. A limited number of printed copies are available from the Clerk's Office for parties in cases not subject to the court's Electronic Case Filing program (ECF).

CASE SCHEDULE -ADR MULTI-OPTION PROGRAM

Date	Event	Governing Rule
3/5/2008	Complaint filed	
5/21/2008	*Last day to: <ul style="list-style-type: none"> meet and confer re: initial disclosures, early settlement, ADR process selection, and discovery plan file Joint ADR Certification with Stipulation to ADR Process or Notice of Need for ADR Phone Conference 	<u>FRCivP 26(f) & ADR L.R.3-5</u> <u>Civil L.R. 16-8</u>
6/4/2008	*Last day to file Rule 26(f) Report, complete initial disclosures or state objection in Rule 26(f) Report and file Case Management Statement per attached Standing Order re Contents of Joint Case Management Statement (also available at http://www.cand.uscourts.gov)	<u>FRCivP 26(a) (1)</u> <u>Civil L.R. 16-9</u>
6/11/2008	INITIAL CASE MANAGEMENT CONFERENCE (CMC) in Courtroom C, 15th Floor, SF at 1:30 PM	<u>Civil L.R. 16-10</u>

* If the Initial Case Management Conference is continued, the other deadlines are continued accordingly.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

STANDING ORDER FOR CIVIL PRACTICE IN CASES
ASSIGNED FOR ALL PURPOSES TO
MAGISTRATE JUDGE EDWARD M. CHEN
(8/9/07)

The parties shall follow the General Orders of the Court for the Northern District of California, the Local Rules, and the Federal Rules of Civil Procedure, except as expressly modified herein. Failure to comply with any of the rules and orders may be deemed sufficient grounds for monetary sanctions, dismissal, entry of default judgment, or other appropriate sanctions. The rules and orders are supplemented and modified as follows:

A. STANDING ORDER RE MOTIONS AND CONFERENCES

1. Criminal Law and Motion is heard on Wednesdays at 9:30 a.m. Civil Law and Motion is heard on Wednesdays at 10:30 a.m. Counsel need not reserve a hearing date in advance for civil motions. However, noticed dates may be reset as the Court's calendar requires.
2. Case Management Conferences are heard on Wednesdays at 1:30 p.m. Pretrial Conferences are heard on Wednesdays at 3:00 p.m.
3. In cases that are randomly assigned to Judge Chen for all purposes, the parties are requested to file their written consent to the assignment of a U.S. Magistrate Judge for all purposes, or their written declination of consent, as soon as possible.
4. All scheduling questions should be addressed to Judge Chen's courtroom deputy, Betty Fong, at (415) 522-2034.
5. Law and motion matters may be submitted without argument upon stipulation of the parties and notification of the Court no later than two (2) court days before the hearing.
6. In all "E-Filing" cases, when filing papers that require the Court to take any action (e.g. motions, meet and confer letters, administrative requests), the parties shall, in addition to filing papers electronically, lodge with chambers a printed copy of the papers on three-hole punch paper (including all exhibits) by the close of the next court day following the day the papers are filed electronically. These printed copies shall be marked "EMC Chambers Copy" and shall be submitted to the Clerk's Office in an envelope clearly marked with the case number, "Magistrate Judge Edward M. Chen," and "E-Filing Chambers Copy." Parties shall not file a paper copy of any document with the Clerk's

Office that has already been filed electronically. A proposed order in an E-Filing case must be emailed to emcpe@cand.uscourts.gov as a WordPerfect attachment on the same day that it is E-Filed. With permission, Chambers' copies of documents may be submitted on CD-ROM with hypertext links to exhibits.

7. The Court can no longer supply a court reporter. If you wish to have this hearing recorded by a court reporter rather than by electronic means, please arrange this privately.

B. STANDING ORDER RE DISCOVERY DISPUTES

This Standing Order applies to all disclosures and discovery motions assigned to Judge Chen and is intended to supplement the Civil Local Rules of this District regarding motion practice (Civil L. R. 7-1 et seq.) and the resolution of disclosure or discovery disputes (Civil L. R. 37-1 et seq.).

8. Discovery motions may be addressed to the Court in three ways. A motion may be noticed on not less than thirty-five (35) days notice pursuant to Civil L. R. 7-2. Alternatively, any party may seek an order shortening time under Civil L. R. 6-3 if the circumstances justify that relief. In emergencies during discovery events (such as depositions), the Court is available pursuant to Civil L. R. 37-1(b). In the event a discovery dispute arises, counsel for the party seeking discovery shall in good faith confer in person with counsel for the party failing to make the discovery in an effort to resolve the dispute without court action, as required by Fed. R. Civ. P. 37 and Civil L. R. 37-1(a). The meeting must be in person, except where good cause is shown why a telephone meeting is adequate. A declaration setting forth these meet and confer efforts, and the final positions of each party, shall be included in the moving papers. The Court will not consider discovery motions unless the moving party has complied with Fed. R. Civ. P. 37 and Civil L. R. 37-1(a).

9. Motions for sanctions shall be filed by separate motion in accordance with the Fed. R. Civ. P. 37 and Civil L. R. 37-3. The parties shall comply with their meet and confer obligations pursuant to Civil L. R. 37-1(a). Parties who refuse to meet and confer will be subject to sanctions pursuant to Civil L. R. 37-3.

10. Any party filing an Emergency or Ex Parte Application must contact Judge Chen's courtroom deputy clerk, Betty Fong, at 415/522-2034.

PRODUCTION OF DOCUMENTS

11. In responding to requests for documents and materials under Fed. R. Civ. P. 34, all parties shall affirmatively state in a written response served on all other parties the full extent to which they will produce materials and shall, promptly after the production, confirm in writing that they have produced all such materials so described that are locatable after a diligent search of all locations at which such materials might plausibly exist. It shall not be sufficient to object and/or to state that "responsive" materials will be or have been produced.

12. In searching for responsive materials in connection with a request under Fed. R. Civ. P. 34, parties must search computerized files, emails, voicemails, work files, desk files, calendars and diaries, and any other locations and sources if materials of the type to be produced might plausibly be expected to be found there.

13. Privilege logs shall be promptly provided and must be sufficiently detailed and informative to justify the privilege. *See* Fed. R. Civ. P. 26(b)(5). No generalized claims of privilege or work product protection shall be permitted. With respect to each communication for which a claim of privilege or work product is made, the asserting party must at the time of its assertion identify: (a) all persons making and receiving the privileged or protected communication; (b) the steps taken to ensure the confidentiality of the communication, including affirmation that no unauthorized persons have received the communication; (c) the date of the communication; and (d) the subject matter of the communication. Failure to furnish this information at the time of the assertion may be deemed a waiver of the privilege or protection.

14. To the maximum extent feasible, all party files and records should be retained and produced in their original form and sequence, including file folders, and the originals should remain available for inspection by any counsel on reasonable notice.

15. As soon as a party has notice of this order, the party shall take such reasonable steps as are necessary to preserve evidence related to the issues presented by the action, including, without limitation, interdiction of any document destruction programs and any ongoing erasures of emails, voicemails, and other electronically recorded material to the extent necessary to preserve information relevant to the issues presented by the action.

16. Except for good cause, no item will be received in evidence if the proponent failed to produce it in the face of a reasonable and proper discovery request covering the item, regardless of whether a motion to overrule any objection thereto was made.

DEPOSITIONS

17. Absent extraordinary circumstances, counsel shall consult in advance with opposing counsel and unrepresented proposed deponents to schedule depositions at mutually convenient times and places. Where an agreement cannot be reached as to any party deponent or

a deponent represented by counsel of record, the following procedure may be invoked by the party seeking any such deposition. The party seeking such a deposition may notice it at least twenty (20) days in advance. If the noticed date and place is unacceptable to the deponent or the deponent's counsel, then within ten (10) days of receipt of the notice, the deponent or counsel for the deponent must reply and counter-propose in writing an alternative date and place falling within twenty (20) days of the date noticed by the party seeking the deposition.

18. Counsel and parties shall comply with Fed. R. Civ. P. 30(d)(1). Deposition objections must be as to privilege or form only. Speaking objections are prohibited. When a privilege is claimed, the witness should nevertheless answer questions relevant to the existence, extent or waiver of the privilege, such as the date of a communication, who made the statement, to whom and in whose presence the statement was made, other persons to whom the contents of the statement have been disclosed, and the general subject matter of the statement, unless such information itself is itself privileged. Private conferences between deponents and attorneys in the course of interrogation, including a line of related questions, are improper and prohibited except for the sole purpose of determining whether a privilege should be asserted.

SANCTIONS

19. Failure to comply with this Order or the Local Rules of this Court may result in sanctions. See Fed. R. Civ. P. 16(f), Civil L. R. 1-4. .
copy.



Edward M. Chen
United States Magistrate Judge

STANDING ORDER FOR ALL JUDGES OF THE NORTHERN DISTRICT OF
CALIFORNIA

CONTENTS OF JOINT CASE MANAGEMENT STATEMENT

Commencing March 1, 2007, all judges of the Northern District of California will require the identical information in Joint Case Management Statements filed pursuant to Civil Local Rule 16-9. The parties must include the following information in their statement which, except in unusually complex cases, should not exceed ten pages:

1. Jurisdiction and Service: The basis for the court's subject matter jurisdiction over plaintiff's claims and defendant's counterclaims, whether any issues exist regarding personal jurisdiction or venue, whether any parties remain to be served, and, if any parties remain to be served, a proposed deadline for service.
2. Facts: A brief chronology of the facts and a statement of the principal factual issues in dispute.
3. Legal Issues: A brief statement, without extended legal argument, of the disputed points of law, including reference to specific statutes and decisions.
4. Motions: All prior and pending motions, their current status, and any anticipated motions.
5. Amendment of Pleadings: The extent to which parties, claims, or defenses are expected to be added or dismissed and a proposed deadline for amending the pleadings.
6. Evidence Preservation: Steps taken to preserve evidence relevant to the issues reasonably evident in this action, including interdiction of any document-destruction program and any ongoing erasures of e-mails, voice mails, and other electronically-recorded material.
7. Disclosures: Whether there has been full and timely compliance with the initial disclosure requirements of Fed. R. Civ. P. 26 and a description of the disclosures made.
8. Discovery: Discovery taken to date, if any, the scope of anticipated discovery, any proposed limitations or modifications of the discovery rules, and a proposed discovery plan pursuant to Fed. R. Civ. P. 26(f).
9. Class Actions: If a class action, a proposal for how and when the class will be certified.
10. Related Cases: Any related cases or proceedings pending before another judge of this court, or before another court or administrative body.
11. Relief: All relief sought through complaint or counterclaim, including the amount of any

damages sought and a description of the bases on which damages are calculated. In addition, any party from whom damages are sought must describe the bases on which it contends damages should be calculated if liability is established.

12. Settlement and ADR: Prospects for settlement, ADR efforts to date, and a specific ADR plan for the case, including compliance with ADR L.R. 3-5 and a description of key discovery or motions necessary to position the parties to negotiate a resolution.

13. Consent to Magistrate Judge For All Purposes: Whether all parties will consent to have a magistrate judge conduct all further proceedings including trial and entry of judgment.

14. Other References: Whether the case is suitable for reference to binding arbitration, a special master, or the Judicial Panel on Multidistrict Litigation.

15. Narrowing of Issues: Issues that can be narrowed by agreement or by motion, suggestions to expedite the presentation of evidence at trial (e.g., through summaries or stipulated facts), and any request to bifurcate issues, claims, or defenses.

16. Expedited Schedule: Whether this is the type of case that can be handled on an expedited basis with streamlined procedures.

17. Scheduling: Proposed dates for designation of experts, discovery cutoff, hearing of dispositive motions, pretrial conference and trial.

18. Trial: Whether the case will be tried to a jury or to the court and the expected length of the trial.

19. Disclosure of Non-party Interested Entities or Persons: Whether each party has filed the "Certification of Interested Entities or Persons" required by Civil Local Rule 3-16. In addition, each party must restate in the case management statement the contents of its certification by identifying any persons, firms, partnerships, corporations (including parent corporations) or other entities known by the party to have either: (i) a financial interest in the subject matter in controversy or in a party to the proceeding; or (ii) any other kind of interest that could be substantially affected by the outcome of the proceeding.

20. Such other matters as may facilitate the just, speedy and inexpensive disposition of this matter.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

NOTICE OF ASSIGNMENT OF CASE
TO A UNITED STATES MAGISTRATE JUDGE FOR TRIAL

Pursuant to General Order 44, the Assignment Plan of the United States District Court for the Northern District of California, this case has been randomly assigned to Magistrate Judge

EDWARD M. CHEN

Pursuant to Title 28 U.S.C. § 636(c), with written consent of all parties, a magistrate judge may conduct all proceedings in the case. Attached is a form to complete if you consent to proceed before the assigned magistrate judge and a form to complete if you decline to proceed before the assigned magistrate judge. Electronic versions of both forms are also available at the Court's Internet site: <http://www.cand.uscourts.gov>. Click on Forms-Civil. A party is free to withhold consent without adverse consequences. If a party declines to consent, the case will be randomly reassigned to a district judge and a case management conference will be scheduled on the district judge's calendar as close as possible to the date presently scheduled before the magistrate judge.

You must file your consent or declination by the deadline for filing the initial case management statement.

The plaintiff or removing party shall serve a copy of this notice and all attachments upon all other parties to this action pursuant to Federal Rules of Civil Procedure 4 and 5.

FOR THE COURT
RICHARD W. WIEKING, CLERK


By: Deputy Clerk

MARY ANN BUCKLEY

EXHIBIT C PAGE 12

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

No. C

Plaintiff(s),

CONSENT TO PROCEED BEFORE A
UNITED STATES MAGISTRATE JUDGE

Defendant(s).

CONSENT TO PROCEED BEFORE A UNITED STATES MAGISTRATE JUDGE

In accordance with the provisions of Title 28, U.S.C. Section 636(c), the undersigned party hereby voluntarily consents to have a United States Magistrate Judge conduct any and all further proceedings in the case, including trial, and order the entry of a final judgment. Appeal from the judgment shall be taken directly to the United States Court of Appeals for the Ninth Circuit.

Dated: _____

Signature: _____

Counsel for _____
(Plaintiff, Defendant or indicate "pro se")

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

No. C

Plaintiff(s),

DECLINATION TO PROCEED BEFORE
A MAGISTRATE JUDGE
AND
REQUEST FOR REASSIGNMENT TO A
UNITED STATES DISTRICT JUDGE

Defendant(s).

REQUEST FOR REASSIGNMENT TO A UNITED STATES DISTRICT JUDGE

The undersigned party hereby declines to consent to the assignment of this case to a United States Magistrate Judge for trial and disposition and hereby requests the reassignment of this case to a United States District Judge.

Dated: _____

Signature _____

Counsel for _____
(Plaintiff, Defendant, or indicate "pro se")

WELCOME TO THE U.S. DISTRICT COURT, SAN FRANCISCO
OFFICE HOURS: 9:00 A.M. TO 4:00 P.M.

415.522.2000

www.cand.uscourts.gov

In Addition to the Local Rules, the Following Guidelines Have Been Provided to Ensure That the Filing Process Is Accomplished with Ease and Accuracy. For Additional Information or Assistance, Please Call the above Number During Office Hours.

1. Documents are to be filed in the Clerk's Office at the location of the chambers of the judge to whom the action has been assigned. We do not accept filings for cases assigned to judges or magistrate judges in the Oakland or San Jose division, per Civil L.R. 3-2(b).
2. This office will retain the original plus one copy of most documents submitted. We will conform as many copies as you bring for your use. Related cases require an extra copy for each related action designated.
3. The copy retained goes directly to the assigned Judge. Courtesy copies, or instructions for couriers to deliver a copy directly to chambers are inappropriate, unless you have been instructed to do so by court order.
4. In order to facilitate the file stamping process, each original document should be submitted on top of its copies. In other words, group like documents together--as opposed to a set of originals and separate sets of copies.
5. The case number must indicate whether it is a civil or criminal matter by the inclusion of C or CR at the beginning of the number. Miscellaneous and foreign judgment matters should also be indicated with initials MISC or FJ at the end of the case number.
6. The case number must include the initials of the judge and/or magistrate judge followed by the letters designating the case Arbitration (ARB), Early Neutral Evaluation (ENE) or Mediation (MED)--if assigned to one of those programs.
7. The document caption should include the appropriate judge or magistrate judge involved in a particular matter or before whom an appearance is being made. This is especially important when submitting Settlement Conference Statements.
8. Documents are to be stapled or acco-fastened at the top. Backings, bindings and covers are not required. Two holes punched at the top of the original document will facilitate processing.
9. Appropriately sized, stamped, self-addressed return envelopes are to be included with proposed orders or when filing documents by mail.

10. Proofs of service should be attached to the back of documents. If submitted separately, you must attach a pleading page to the front of the document showing case number and case caption.
11. There are no filing fees once a case has been opened.
12. New cases must be accompanied by a completed and signed Civil Cover Sheet, the filing fee or fee waiver request form and an original plus two copies of the complaint and any other documents. For Intellectual Property cases, please provide an original plus three copies of the complaint. Please present new cases for filing before 3:30 p.m., as they take a considerable amount of time to process.
13. Copies of forms may be obtained at no charge. They may be picked up in person from the Clerk's Office forms cabinet or with a written request accompanied by an appropriate sized, stamped, self-addressed envelope for return. In addition, copies of the Local Rules may be obtained, free of charge, in the Clerk's Office or by sending a written request, along with a self-addressed, 10" x 14" return envelope, stamped with \$ 3.95 postage to: Clerk, U.S. District Court, 450 Golden Gate Avenue, 16th Floor, San Francisco, CA 94102.
14. Two computer terminals which allow public access to case dockets and one terminal with information regarding files at the Federal Records Center (FRC) are located in the reception area of the Clerk's Office. Written instructions are posted by the terminals. Outside of the Clerk's Office, electronic access to dockets is available through PACER. To obtain information or to register call 1-800-676-6851.
15. A file viewing room is located adjacent to the reception area. Files may be viewed in this area after signing the log sheet and presenting identification. Files are to be returned by 1:00 pm. Under no circumstances are files to be removed from the viewing room.
16. The Clerk's Office can only accept payment by exact change or check made payable to Clerk, U.S. District Court. No change can be made for fees or the public copy machine.
17. Two pay copy machines are located in the file viewing room for public use, at fifteen cents (\$.15) per page. Copy cards may be purchases at the snack bar on the first floor. Orders for copywork may be placed through Eddie's Document Retrieval by phoning 415-317-5556. Arrangements may be made to bring in a personal copier by calling the Clerk's Office in advance.
18. We have a drop box for filing when the Clerk's Office is closed. Please see attached for availability and instructions.

SAN FRANCISCO

Article III Judges	Judges Initials	Magistrate Judges	Judges Initials
Alsup, William H.	WHA	Chen, Edward M.	EMC
Breyer, Charles R.	CRB	James, Maria-Elena	MEJ
Chesney, Maxine M.	MMC	Laporte, Elizabeth D.	EDL
Conti, Samuel	SC	Larson, James	JL
Hamilton, Phyllis J.	PJH	Spero, Joseph C.	JCS
Henderson, Thelton E.	TEH	Zimmerman, Bernard	BZ
Illston, Susan	SI		
Jenkins, Martin J.	MJJ		
Patel, Marilyn Hall	MHP		
Schwarzer, William W	WWS		
Walker, Vaughn R	VRW		
White, Jeffrey S.	JSW		

SAN JOSE

Article III Judges	Judges Initials	Magistrate Judges	Judges Initials
Fogel, Jeremy	JF	Lloyd, Howard R.	HRL
Ware, James	JW	Seeborg, Richard	RS
Whyte, Ronald M.	RMW	Trumbull, Patricia V.	PVT

OAKLAND

Article III Judges	Judges Initials	Magistrate Judges	Judges Initials
Armstrong, Sandra B.	SBA	Brazil, Wayne D.	WDB
Jensen, D. Lowell	DLJ		
Wilken, Claudia	CW		

San Francisco	16th Floor	building closed between 6PM and 6AM	more info 415-522-2000
San Jose	2nd Floor	building closed between 5PM and 7:30AM	more info 408-535-5364
Oakland	1st Floor	building closed between 5:00 PM and 7:00 AM	more info 510-637-3530

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

DROP BOX FILING PROCEDURES

1. The drop box, located outside the Clerk's Office (see above chart), is available for the filing of documents before 9:00 a.m. and after 4:00 p.m. weekdays. Please note that access to the federal building is limited to 'normal business hours' (as noted in the chart above).
2. The drop box may not be used for the filing of any briefs in support of, or in opposition to, any matter scheduled for a hearing within 7 calendar days. All such documents must be filed in the Clerk's Office during regular office hours by the date due.
3. Using the electronic file stamping machine located next to the drop box, stamp each original document "Received" on the back side of the last page. Clerk's Office employees empty the box once each court day when the Clerk's Office opens to the public. The "Filed" date, which will be placed on original documents by Intake personnel, will be the same as the "Received" date, unless the "Received" date is a weekend or Court holiday. In those instances, the "Filed" date will be the first court day following the weekend or holiday. Documents placed in the drop box without a "Received" stamp will be filed as of the day the box is next emptied.
4. After stamping each original and enclosing one copy for the court,* the documents must be placed in an orange court mailing pouch or red Expando folder provided for your convenience. *To facilitate processing of your documents, each original document should be submitted on top of its copies.* Prior to placing the pouch or folder in the drop box, please insert in the pouch or folder window a fully completed Drop Box Filing Information Card. You may use more than one pouch or folder per filing, but a separate Information Card must be enclosed for each one.
(*Please note that the Clerk's Office will retain two copies of all new complaints relating to patents, trademarks and copyrights.)
5. If you wish us to mail you one or more conformed copies that you have provided, you must enclose an appropriately sized, self-addressed, stamped envelope with adequate return postage. Alternatively, if you would like to pick up conformed copies, please mark your return envelope "FOR MESSENGER PICK UP BY: (NAME, FIRM)." Your copies will be available for pick-up after 2:00 p.m. on the day the drop box is emptied.
6. A filing fee, if required, may be paid by check or money order, payable to "Clerk, U.S. District Court" in an exact amount. *Please do not enclose cash.*
7. Documents deposited in the drop box must be in compliance with all local and federal rules, as appropriate. Documents filed "Under Seal" must be submitted in compliance with Civil L.R. 79-5.

EXHIBIT “D”

Lawrence J. Gornick (SBN 136290)
Debra DeCarli (SBN 237642)
LEVIN SIMES KAISER & GORNICK LLP
44 Montgomery Street, 36th Floor
San Francisco, CA 94104
Telephone: (415) 646-7160
Fax: (415) 981-1270
lgornick@lskg-law.com
ddecarli@lskg-law.com

Attorneys for Plaintiffs

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION**

JOE V. SANCHEZ and SANDRA L.
ROARTY-SANCHEZ,

Plaintiffs,

vs.

BAYER HEALTHCARE
PHARMACEUTICALS, INC.; BAYER
HEALTHCARE LLC; GENERAL ELECTRIC
COMPANY; GE HEALTHCARE, INC.;
TYCO INTERNATIONAL, INC.; COVIDIEN,
INC.; TYCO HEALTHCARE GROUP, LP;
MALLINCKRODT, INC.; and BRACCO
DIAGNOSTICS, INC.

Defendants.

Case No:

CV 08 0973

ORIGINAL COMPLAINT

DEMAND FOR JURY TRIAL

Plaintiffs, Joe V. Sanchez and Sandra L. Roarty-Sanchez, (hereinafter "Plaintiffs") allege as follows:

NATURE OF THE CASE

1. Plaintiff Joe V. Sanchez ("Mr. Sanchez" or "Plaintiff") has nephrogenic systemic fibrosis ("NSF"). NSF is an incurable, painful, and deadly disease. Mr. Sanchez contracted NSF as a result of receiving intravenous injections of gadolinium-based contrast agents manufactured by the Defendants. Gadolinium-based contrast agents are not safe for use in individuals such as Plaintiff who have impaired kidney function. Defendants represented that the gadolinium-based contrast agents were safe and failed to warn of the risks associated with gadolinium-based contrast agents.

JURISDICTION AND VENUE

2. This Court has jurisdiction pursuant to 28 USC § 1332. Plaintiffs are citizens of a state that is different from the states where Defendants are incorporated and have their respective principal places of business. The amount in controversy for this case exceeds \$75,000. Venue pursuant to 28 USC § 1391(c) is proper because Defendants have sufficient contacts within the City and County of San Francisco, California to subject each of them to personal jurisdiction.

INTRADISTRICT ASSIGNMENT

3. On information and belief, a substantial part of the events or omissions which give rise to the claim occurred in the County and City of San Francisco.

PARTIES

Plaintiffs

4. Joe V. Sanchez and his wife Sandra L. Roarty-Sanchez are residents of the State of Arizona.

Defendants

5. Defendants Bayer HealthCare Pharmaceuticals, Inc. and Bayer Healthcare LLC (jointly referred to as "Bayer") manufacture, market, and sell Magnevist, a gadolinium-based contrast agent that, on information and belief, was injected into Plaintiff.

6. Defendant Bayer HealthCare LLC is a Delaware business entity with its principal place of business in New York.

7. Defendant Bayer HealthCare Pharmaceuticals, Inc. is a Delaware business entity with its principal place of business in New Jersey. Defendant Bayer HealthCare Pharmaceuticals, Inc. is the U.S.-based pharmaceuticals unit of Bayer Healthcare LLC.

8. At all times relevant to this complaint, Bayer was in the business of designing, licensing, manufacturing, distributing, selling, marketing, promoting, and introducing Magnevist into interstate commerce.

9. Defendants General Electric Company and GE Healthcare, Inc. (jointly referred to as "GE") manufacture, market, and sell Omniscan, a gadolinium-based contrast agent that, on information and belief, was injected into Plaintiff.

1 10. Defendant General Electric Company is a New York business entity with its principal
2 place of business in Connecticut.

3 11. Defendant GE Healthcare, Inc. is a Delaware corporation with its principal place of
4 business in New Jersey.

5 12. At all times relevant to this complaint, GE was in the business of designing, licensing,
6 manufacturing, distributing, selling, marketing, promoting, and introducing Omniscan into interstate
7 commerce.

8 13. Defendants Tyco International Inc., Covidien Inc., Tyco Healthcare Group LP, and
9 Mallinckrodt, Inc. (collectively referred to as "Tyco") manufacture, market, and sell OptiMARK, a
10 gadolinium-based contrast agent that, on information, and belief, was injected into Plaintiff.

11 14. Defendant Tyco International Inc. is a Massachusetts corporation with its principal
12 place of business in New Jersey.

13 15. Defendant Covidien Inc. is a Delaware corporation with its principal place of business
14 in New Hampshire. Tyco Healthcare Group LP was a Delaware corporation with its principal place of
15 business in Massachusetts. Tyco Healthcare LP was a subsidiary of Tyco International until
16 approximately July 2007, when Tyco Healthcare LP became Covidien Inc. and separated from Tyco
17 International.

18 16. Defendant Mallinckrodt, Inc. is a Delaware corporation with its principal place of
19 business in Missouri. Mallinckrodt was a business unit of Tyco Healthcare LP and is currently a
20 business unit of Covidien Inc.

21 17. At all times relevant to this complaint, Tyco was in the business of designing, licensing,
22 manufacturing, distributing, selling, marketing, promoting, and introducing OptiMARK into interstate
23 commerce.

24 18. Defendant Bracco Diagnostics, Inc. ("Bracco") manufactures, markets, and sells
25 MultiHance and ProHance, gadolinium-based contrast agents that, on information and belief, were
26 injected into Plaintiff.

27 19. Bracco Diagnostics, Inc. is a Delaware corporation with its principal place of business
28 in New Jersey.

FACTS

23. NSF is predominantly characterized by discoloration, thickening, tightening, and swelling of the skin after receiving a gadolinium-based contrast agent injection. These fibrotic and edematous changes produce muscular weakness and inhibit flexion and extension of joints, resulting in contractures. NSF often progresses to painful inhibition of the ability to use the arms, legs, hands, feet, and other joints. The skin changes that begin as darkened patches or plaques progress to a "woody" texture and are accompanied by burning, itching, or severe pain in the areas of involvement. NSF also progresses to a fibrotic or scarring condition of other body organs such as the lungs, heart, liver, and musculature, and that can inhibit their ability to function properly and may lead to death. NSF is a progressive disease for which there is no known cure.

25. Gadolinium is a highly toxic heavy metal. It does not occur naturally in the human body. The only known route for gadolinium to enter the human body is injection of a gadolinium-based contrast agent.

27. Gadolinium is eliminated from the body by the kidneys. Gadolinium-based contrast agents are not safe if the chelate separates from the gadolinium, which is what happens over time if kidneys are not functioning properly. Individuals with impaired kidney function risk dechelation, and cannot efficiently or quickly eliminate gadolinium from their bodies. Defendants never tested the safety of their gadolinium-based contrast agents in individuals with kidney impairment.

1 28. On information and belief, the gadolinium-based contrast agents injected into Plaintiff
2 were manufactured by Defendants.

3 29. In pre-clinical studies during which gadolinium-based contrast agents were injected into
4 laboratory animals, consistent patterns of toxicity including nephrogenic fibrotic changes in the
5 kidneys and other body organs occurred.

6 30. During the years that Defendants have manufactured, marketed, distributed, sold, and
7 administered gadolinium-based contrast agents, there have been numerous case reports, studies,
8 assessments, papers,, and other clinical data that have described and/or demonstrated NSF in
9 connection with the use of gadolinium-based contrast agents.

10 31. Plaintiff received MRIs and/or MRAs utilizing gadolinium-based contrast agents.

11 32. Plaintiff had impaired kidney function at the time he received his first injection of
12 gadolinium-based contrast agent and continued to have impaired kidney function at the time he
13 received each subsequent injection of gadolinium-based contrast agent.

14 33. During the time period when Plaintiff received injections of Defendants' gadolinium-
15 based contrast agents, Defendants knew or should have known that the use of gadolinium-based
16 contrast agents created a risk of serious bodily injury and death in patients with impaired kidney
17 function.

18 34. Defendants failed to warn Plaintiff and his prescribing physicians about the serious
19 health risks associated with gadolinium-based contrast agents, and failed to disclose the fact that there
20 were safer alternatives.

21 35. As a direct and proximate result of receiving injections of gadolinium-based contrast
22 agents manufactured, marketed, distributed, and sold by Defendants, Plaintiff developed NSF.

23 36. Defendants have repeatedly and consistently failed to advise consumers and/or their
24 healthcare providers of the causal relationship between gadolinium-based contrast agents and NSF in
25 patients with kidney impairment. Defendants knew or should have known of the risk of NSF posed by
26 gadolinium-based contrast agents to individuals with impaired kidney function years before they
27 finally issued warnings.

28 37. It was not until September 2007 that Bayer, GE, Bracco, and Mallinckrodt finally sent

1 letters to healthcare providers warning them of the risk of NSF to kidney impaired individuals who
2 received MRIs using gadolinium-based contrast agents.

3 38. Had Plaintiff and/or his healthcare providers been warned about the risks associated
4 with gadolinium-based contrast agents, he would not have been administered gadolinium-based
5 contrast agents and would not have been afflicted with NSF.

6 39. As a direct and proximate result of Plaintiff being administered gadolinium-based
7 contrast agents, he has suffered severe physical injury and pain and suffering, including, but not
8 limited to, the effects of NSF. Plaintiff's physical injuries and pain and suffering will inevitably
9 worsen over time and will in all likelihood lead to death.

10 40. As a direct and proximate result of being administered gadolinium-based contrast
11 agents, Plaintiffs suffered and continue to suffer significant mental anguish and emotional distress and
12 will continue to suffer significant mental anguish and emotional distress in the future.

13 41. As a direct and proximate result of being administered gadolinium-based contrast
14 agents, Plaintiffs have also incurred medical expenses and other economic damages and will continue
15 to incur such expenses in the future.

16 **DISCOVERY RULE & FRAUDULENT CONCEALMENT**

17 42. The discovery rule should be applied to toll the running of the statute of limitations
18 until Plaintiffs knew or through the exercise of reasonable care and diligence should have known of
19 the existence of their claims against all Defendants. The nature of Plaintiffs' injuries and damages,
20 and their relationship to gadolinium-based contrast agents used in conjunction with MRIs and MRAs,
21 was not discovered, and through reasonable care and due diligence could not have been discovered, by
22 Plaintiffs, until a time less than two years before the filing of this Complaint. Therefore, under
23 appropriate application of the discovery rule, Plaintiffs' suit was filed well within the applicable
24 statutory limitations period.

25 43. Defendants are estopped from asserting a statute of limitations defense because all
26 Defendants fraudulently concealed from Plaintiffs the nature of Plaintiffs' injury and the connection
27 between the injury and all Defendants' tortious conduct.
28

FIRST CAUSE OF ACTION

STRICT LIABILITY: FAILURE TO WARN

44. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

45. Defendants' gadolinium-based contrast agents, and MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents; were defective due to inadequate warnings or instruction for use, both prior to marketing and post-marketing. Defendants knew or should have known that their products created significant risks of serious bodily harm and death to consumers. Defendants failed to adequately warn consumers and their healthcare providers of such risks.

46. Because of Defendants' failure to provide adequate warnings with their products, Plaintiff was injected with gadolinium-based contrast agents which the Defendants manufactured, designed, sold, supplied, marketed or otherwise introduced into the stream of commerce. Those gadolinium-based contrast agents are the legal cause of Plaintiff's physical injuries, harm, damages, and economic loss. Plaintiffs will continue to suffer such harm, damages, and economic loss in the future.

SECOND CAUSE OF ACTION

STRICT LIABILITY: DESIGN DEFECT

47. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

48. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of gadolinium-based contrast agents, and MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents.

49. The gadolinium-based contrast agents manufactured and supplied by Defendants were defective in design or formulation in that, when they left the hands of the Defendants, the foreseeable risks of the products exceeded the benefits associated with their design or formulation, or were more dangerous than an ordinary consumer would expect.

50. The foreseeable risks associated with the design or formulation of gadolinium-based contrast agents, and MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents, include, but are not limited to, the fact that the design or formulation of

1 gadolinium-based contrast agents are more dangerous than a reasonably prudent consumer would
2 expect when used in an intended or reasonably foreseeable manner.

3 51. As a direct and proximate result of Plaintiff being administered gadolinium-based
4 contrast agents as manufactured, designed, sold, supplied, marketed, and introduced into the stream of
5 commerce by Defendants, Plaintiff has suffered physical injury, harm, damages, and economic loss
6 and will continue to suffer such harm, damages, and economic loss in the future.

7 **THIRD CAUSE OF ACTION**

8 **STRICT LIABILITY: FAILURE TO ADEQUATELY TEST**

9 52. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

10 53. Defendants advised consumers and the medical community that gadolinium-based
11 contrast agents were safe for use. Defendants failed to adequately test gadolinium-based contrast
12 agents with respect to their use by consumers with kidney impairment.

13 54. Had Defendants adequately tested the safety of gadolinium-based contrast agents for
14 use by consumers with kidney impairment and disclosed those results to the medical community or the
15 public, Plaintiff would not have been administered gadolinium-based contrast agents.

16 55. As a direct and proximate result of Defendants' failure to adequately test the safety of
17 gadolinium-based contrast agents and as a direct and proximate result of Plaintiff being administered
18 gadolinium-based contrast agents as manufactured, designed, sold, supplied, marketed, and introduced
19 into the stream of commerce by Defendants, Plaintiff has suffered physical injury, harm, damages, and
20 economic loss and will continue to suffer such harm, damages, and economic loss in the future.

21 **FOURTH CAUSE OF ACTION**

22 **NEGLIGENCE**

23 56. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

24 57. Defendants had a duty to exercise reasonable care in the design, formulation, testing,
25 manufacture, labeling, marketing, sale and/or distribution of gadolinium-based contrast agents and the
26 MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents.
27 In particular, they had a duty to assure that their products did not pose an unreasonable risk of bodily
28 harm and adverse events.

1 58. Defendants failed to exercise reasonable care in the design, formulation, manufacture,
2 sale, testing, marketing, or distribution of gadolinium-based contrast agents and the MRI and MRA
3 machines designed to be used in conjunction with gadolinium-based contrast agents in that they knew
4 or should have known that the products could cause significant bodily harm or death and were not safe
5 for use by certain types of consumers.

6 59. Defendants failed to exercise ordinary care in the labeling of gadolinium-based contrast
7 agents and the labeling of MRI and MRA machines designed to be used in conjunction with
8 gadolinium-based contrast agents and failed to issue to consumers and their health care providers
9 adequate warnings concerning the risks of serious bodily injury or death due to the use of gadolinium-
10 based contrast agents and the MRI and MRA machines designed to be used in conjunction with
11 gadolinium-based contrast agents.

12 60. Despite the fact that Defendants knew or should have known that gadolinium-based
13 contrast agents and the MRI and MRA machines designed to be used in conjunction with gadolinium-
14 based contrast agents posed a serious risk of bodily harm to consumers, Defendants unreasonably
15 continued to manufacture and market gadolinium-based contrast agents and the MRI and MRA
16 machines designed to be used in conjunction with gadolinium-based contrast agents for administration
17 to MRI and MRA patients with kidney impairment and failed to exercise reasonable care with respect
18 to post-sale warnings and instructions for safe use.

19 61. At all relevant times, it was foreseeable to Defendants that consumers like Plaintiff
20 would suffer injury as a result of their failure to exercise ordinary care as described above.

21 62. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered
22 physical injuries, harm, damages, and economic loss and will continue to suffer such harm, damages
23 and economic loss in the future.

24 63. The foregoing acts, conduct and omissions of Defendants were vile, base, willful,
25 malicious, wanton, oppressive, and fraudulent, and were done with a conscious disregard for the
26 health, safety, and rights of Plaintiffs and other users of Defendants' products, and for the primary
27 purpose of increasing Defendants' profits. As such, Plaintiffs are entitled to exemplary damages.

28 /// /// /// ///

FIFTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

64. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

65. Defendants supplied the public and Plaintiff's healthcare providers with materially false and incomplete information with respect to the safety of their gadolinium-based contrast agents.

66. The false information supplied by Defendants was that gadolinium-based contrast agents were safe.

67. In supplying this false information, Defendants failed to exercise reasonable care.

68. The false information communicated by Defendants to Plaintiff and his healthcare providers was material and Plaintiff justifiably relied in good faith on the information to his detriment.

69. As a direct and proximate result of Defendants' misrepresentations, Plaintiff was administered gadolinium-based contrast agents and has suffered physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

SIXTH CAUSE OF ACTION

FRAUD

70. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

71. Defendants knowingly and intentionally made materially false and misleading representations to Plaintiff's healthcare providers and to the public, to the effect that gadolinium-based contrast agents were safe for use and that their labeling, marketing, and promotional materials fully described all known risks associated with their product.

72. Defendants' representations were in fact false. Gadolinium-based contrast agents are not safe for use and Defendants' labeling, marketing, and promotional materials did not fully describe all known risks of the products.

73. Defendants had actual knowledge that gadolinium-based contrast agents created an unreasonable risk of serious bodily injury and death to consumers, especially patients with kidney impairment.

1 74. Defendants knowingly and intentionally omitted this information from their labeling,
2 marketing, and promotional materials and instead, labeled, promoted, and marketed their products as
3 safe for use in order to increase and sustain sales.

4 75. When Defendants made representations that gadolinium-based contrast agents were
5 safe for use, they knowingly and intentionally concealed and withheld from Plaintiff, his physicians,
6 and the public, the fact that their gadolinium-based contrast agents are not safe for use in consumers
7 with kidney impairment.

8 76. Defendants had a duty to disclose that gadolinium-based contrast agents are not safe for
9 use in patients with kidney impairment. Defendants had superior knowledge of these facts that were
10 material to Plaintiff and his physicians' decisions to use gadolinium-based contrast agents.

11 77. Plaintiff and his healthcare providers reasonably and justifiably relied on the
12 Defendants' representations that gadolinium-based contrast agents were safe for human use and that
13 Defendants' labeling, marketing, and promotional materials fully described all known risks associated
14 with the products.

15 78. Plaintiff did not know, and could not have learned of the facts that the Defendants
16 omitted and suppressed. The facts suppressed and concealed by the Defendants are material. Had
17 Plaintiff and his healthcare providers known that gadolinium-based contrast agents are not safe for use
18 in patients with renal insufficiency, Plaintiff would not have been injected with gadolinium-based
19 contrast agents.

20 79. As a direct and proximate result of Defendants' misrepresentations and concealment,
21 Plaintiff was administered gadolinium-based contrast agents and has suffered physical injury, harm,
22 damages and economic loss and will continue to suffer such harm, damages, and economic loss in the
23 future.

24 80. The foregoing acts, conduct, and omissions of Defendants were vile, base, willful,
25 malicious, wanton, oppressive, and fraudulent, and were done with a conscious disregard for the
26 health, safety, and rights of Plaintiff and other users of Defendants' products, and for the primary
27 purpose of increasing Defendants' profits. As such Plaintiffs are entitled to exemplary damages.

28 /// /// /// ///

SEVENTH CAUSE OF ACTION

FRAUD: CONCEALMENT, SUPPRESSION OR

OMISSION OF MATERIAL FACTS

81. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

82. Defendants omitted, suppressed, or concealed material facts concerning the dangers and risk associated with the use of their gadolinium-based contrast agents, including but not limited to the risks to patients with kidney impairment of developing NSF, and the fact that safer alternatives were available. Further, Defendants purposely downplayed and understated the serious nature of the risks associated with use of their gadolinium-based contrast agents in order to increase and sustain sales.

83. As a direct and proximate result of Defendants' concealment of material facts, Plaintiff was administered gadolinium-based contrast agents and has suffered physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

84. The foregoing acts, conduct, and omissions of Defendants were vile, base, willful, malicious, wanton, oppressive, and fraudulent, and were done with a conscious disregard for the health, safety, and rights of Plaintiff and other users of Defendants' products, and for the primary purpose of increasing Defendants' profits. As such Plaintiffs are entitled to exemplary damages.

EIGHTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

85. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

86. Defendants expressly warranted that gadolinium-based contrast agents were safe and effective.

87. The gadolinium-based contrast agents manufactured and sold by Defendants did not conform to these express representations because they cause serious injury to consumers when administered in recommended dosages.

88. As a direct and proximate result of Defendants' breach of warranty, Plaintiff has suffered physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

NINTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

89. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

90. At the time Defendants designed, manufactured, marketed, sold, and distributed gadolinium-based contrast agents, Defendants knew of the use for which gadolinium-based contrast agents was intended and impliedly warranted the product to be of merchantable quality and safe for such use.

91. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether gadolinium-based contrast agents were of merchantable quality and safe for their intended use and upon Defendants' implied warranty as to such matters.

92. Contrary to such implied warranty, gadolinium-based contrast agents were not of merchantable quality or safe for their intended use because the product was unreasonably dangerous as described above.

93. As a direct and proximate result of Defendants' breach of warranty, Plaintiff has suffered physical injury, harm, damages,, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

TENTH CAUSE OF ACTION

VIOLATION OF ARIZONA CONSUMER PROTECTION STATUTES

94. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

95. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. Ann. §§ 44-1521 *et seq.* including but not limited to the following:

a. Marketing, promoting or selling Magnevist, Omniscan, OptiMark, MultiHance, or ProHance for use with MRAs and other off-label uses by impliedly representing that such products are approved for use with MRAs and other off-label uses, when in fact there is no such approval;

b. Representing that gadolinium-based contrast agents are safe and effective for all patients, including patients with kidney impairment, when in fact they are not;

c. Representing that MRIs and MRAs using gadolinium-based contrast agents are safer or more effective than other imaging methods that do not require the use of gadolinium-based contrast

agents when in fact they are not;

d. Marketing, promoting, or selling their products as safer or superior to other brands of gadolinium-based contrast agents;

e. Marketing, promoting or selling Magnevist, Omniscan, OptiMark, MultiHance, or ProHance as inert or with words to that effect;

f. Marketing, promoting or selling Magnevist, Omniscan, OptiMark, MultiHance, or ProHance for use with MRAs or other off-label uses by expressly or impliedly representing that they are safe for such use; and

g. Remaining silent despite their knowledge of the growing body of evidence regarding the danger of NSF and doing so because the prospect of huge profits outweighed health and safety issues.

96. As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive actions or practices, Plaintiff was administered gadolinium-based contrast agents and has suffered serious physician injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

ELEVENTH CAUSE OF ACTION

LOSS OF CONSORTIUM

97. Plaintiff Sandra L. Roarty-Sanchez ("Mrs. Sanchez") incorporates by reference and realleges each paragraph set forth above.

98. Sandra L. Roarty-Sanchez is the wife of Joe V. Sanchez.

99. As a direct and proximate result of Defendants conducts, Mrs. Sanchez has been deprived of her husband's love, society, companionship, and services and has otherwise suffered loss, the extent of which will be more fully adduced at the trial of this matter.

WHEREFORE, Plaintiffs pray for relief as follows:

1. Compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, loss of consortium, and other non-economic damages in an amount to be determined at trial of this action;

2. Past and future medical expenses, income, and other economic damages in an amount to be determined at trial of this action;
3. Punitive damages in an amount to be determined at trial of this action;
4. Pre- and post-judgment interest;
5. Attorneys' fees, expenses, and costs; and
6. Such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury.

Respectfully submitted this 15th day of February, 2008.

LEVIN SIMES KAISER & GORNICK LLP

By: 

Lawrence J. Gornick, Esq.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

NOTICE OF ASSIGNMENT OF CASE
TO A UNITED STATES MAGISTRATE JUDGE FOR TRIAL

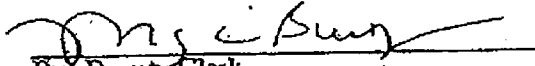
Pursuant to General Order 44, the Assignment Plan of the United States District Court for the Northern District of California, this case has been randomly assigned to Magistrate Judge **EDWARD M. CHEN**.

Pursuant to Title 28 U.S.C. § 636(c), with written consent of all parties, a magistrate judge may conduct all proceedings in the case. Attached is a form to complete if you consent to proceed before the assigned magistrate judge and a form to complete if you decline to proceed before the assigned magistrate judge. Electronic versions of both forms are also available at the Court's Internet site: <http://www.cand.uscourts.gov>. Click on Forms-Civil. A party is free to withhold consent without adverse consequences. If a party declines to consent, the case will be randomly reassigned to a district judge and a case management conference will be scheduled on the district judge's calendar as close as possible to the date presently scheduled before the magistrate judge.

You must file your consent or declination by the deadline for filing the initial case management statement.

The plaintiff or removing party shall serve a copy of this notice and all attachments upon all other parties to this action pursuant to Federal Rules of Civil Procedure 4 and 5.

FOR THE COURT
RICHARD W. WIEKING, CLERK


By: Deputy Clerk

MARY ANN BUCKLEY

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

No. C

Plaintiff(s),

CONSENT TO PROCEED BEFORE A
UNITED STATES MAGISTRATE JUDGE

v.

Defendant(s).

CONSENT TO PROCEED BEFORE A UNITED STATES MAGISTRATE JUDGE

In accordance with the provisions of Title 28, U.S.C. Section 636(c), the undersigned party hereby voluntarily consents to have a United States Magistrate Judge conduct any and all further proceedings in the case, including trial, and order the entry of a final judgment. Appeal from the judgment shall be taken directly to the United States Court of Appeals for the Ninth Circuit.

Dated: _____

Signature _____

Counsel for _____
(Plaintiff, Defendant or indicate "pro se")

1
2
3
4
5
6
7
8 UNITED STATES DISTRICT COURT
9 NORTHERN DISTRICT OF CALIFORNIA
10

11 No. C .

12 Plaintiff(s),

DECLINATION TO PROCEED BEFORE
A MAGISTRATE JUDGE

13 AND

14 REQUEST FOR REASSIGNMENT TO A
15 UNITED STATES DISTRICT JUDGE

16 Defendant(s).
17

18 REQUEST FOR REASSIGNMENT TO A UNITED STATES DISTRICT JUDGE

19 The undersigned party hereby declines to consent to the assignment of this case to a United
20 States Magistrate Judge for trial and disposition and hereby requests the reassignment of this case to
21 a United States District Judge.

22 Dated: _____

Signature _____

23 Counsel for _____
24 (Plaintiff, Defendant, or indicate "pro se")
25
26
27
28

CV 08

0973

EM

ADR

U.S. District Court Northern California

ECF Registration Information Handout

The case you are participating in has been designated for this court's Electronic Case Filing (ECF) Program, pursuant to Civil Local Rule 5-4 and General Order 45. This means that you must (check off the boxes ☒ when done):

- ☐ 1) Serve this ECF Registration Information Handout on **all** parties in the case along with the complaint, or for removals, the removal notice. **DO NOT** serve the efiler application form, just this handout.

Each attorney representing a party must also:

- ☐ 2) **Register** to become an efiler by filling out the efiler application form. Follow **ALL** the instructions on the form carefully. If you are already registered in this district, do not register again, your registration is valid for life on all ECF cases in this district.
- ☐ 3) **Email** (do not efile) the complaint and, for removals, the removal notice and all attachments, in PDF format within ten business days, following the instructions below. You do not need to wait for your registration to be completed to email the court.
- ☐ 4) Access dockets and documents using **PACER** (Public Access to Court Electronic Records). If your firm already has a PACER account, please use that - it is not necessary to have an individual account. PACER registration is free. If you need to establish or check on an account, visit: <http://pacer.psc.uscourts.gov> or call (800) 676-6856.

BY SIGNING AND SUBMITTING TO THE COURT A REQUEST FOR AN ECF USER ID AND PASSWORD, YOU CONSENT TO ENTRY OF YOUR E-MAIL ADDRESS INTO THE COURT'S ELECTRONIC SERVICE REGISTRY FOR ELECTRONIC SERVICE ON YOU OF ALL E-FILED PAPERS, PURSUANT TO RULES 77 and 5(b)(2)(D) (eff. 12.1.01) OF THE FEDERAL RULES OF CIVIL PROCEDURE.

All subsequent papers submitted by attorneys in this case shall be filed electronically. Unrepresented litigants must file and serve in paper form, unless prior leave to file electronically is obtained from the assigned judge.

ECF registration forms, interactive tutorials and complete instructions for efilings may be found on the ECF website: <http://ecf.cand.uscourts.gov>

Submitting Initiating Documents

PDF versions of all the initiating documents originally submitted to the court (Complaint or Notice of Removal, exhibits, etc.) must be **emailed (not efiled)** to the **PDF email box for the presiding judge** (not the referring judge, if there is one) **within 10 (ten) business days** of the opening of your case. For a complete list of the email addresses, please go to: <http://ecf.cand.uscourts.gov> and click on **[Judges]**.

You must include the case number and judge's initials in the subject line of all relevant emails to the court. You do not need to wait for your registration to email these documents.

These documents must be emailed instead of e-filed to prevent duplicate entries in the ECF system. All other documents must be e-filed from then on. You do not need to efile or email the Civil Cover Sheet, Summons, or any documents issued by the court at case opening; note that you do need to efile the Summons Returned.

Converting Documents to PDF

Conversion of a word processing document to a PDF file is required before any documents may be submitted to the Court's electronic filing system. Instructions for creating PDF files can be found at the ECF web site: <http://ecf.cand.uscourts.gov>, and click on **[FAQ]**.

Email Guidelines: When sending an email to the court, the subject line of the email **must** contain the **case number, judge's initials** and the **type of document(s)** you are sending, and/or the topic of the email.

Examples: The examples below assume your case number is 03-09999 before the Honorable Charles R. Breyer:

Type of Document	Email Subject Line Text
Complaint Only	03-09999 CRB Complaint
Complaint and Notice of Related Case	03-09999 CRB Complaint, Related Case
Complaint and Motion for Temporary Restraining Order	03-09999 CRB Complaint, TRO

Questions

Almost all questions can be answered in our FAQs at <http://ecf.cand.uscourts.gov>, please check them first.

You may also email the ECF Help Desk at ECFhelpdesk@cand.uscourts.gov or call the toll-free ECF Help Desk number at: (866) 638-7829.

The ECF Help Desk is staffed Mondays through Fridays from 9:00am to 4:00pm Pacific time, excluding court holidays.

JOE V SANCHEZ,

Plaintiff (s),

v.

BAYER HEALTHCARE,

Defendant(s).

No. C 08-00973 EMC

ORDER SETTING INITIAL CASE
MANAGEMENT CONFERENCE
AND ADR DEADLINES

E-filing

IT IS HEREBY ORDERED that this action is assigned to the Honorable Edward M. Chen. When serving the complaint or notice of removal, the plaintiff or removing defendant must serve on all other parties a copy of this order, the Notice of Assignment of Case to a United States Magistrate Judge for Trial, and all other documents specified in Civil Local Rule 4-2. Counsel must comply with the case schedule listed below unless the Court otherwise orders.

IT IS FURTHER ORDERED that this action is assigned to the Alternative Dispute Resolution (ADR) Multi-Option Program governed by ADR Local Rule 3. Counsel and clients shall familiarize themselves with that rule and with the material entitled "Dispute Resolution Procedures in the Northern District of California" on the Court ADR Internet site at www.adr.cand.uscourts.gov. A limited number of printed copies are available from the Clerk's Office for parties in cases not subject to the court's Electronic Case Filing program (ECF).

CASE SCHEDULE -ADR MULTI-OPTION PROGRAM

Date	Event	Governing Rule
2/15/2008	Complaint filed	
4/30/2008	*Last day to: <ul style="list-style-type: none">meet and confer re: initial disclosures, early settlement, ADR process selection, and discovery planfile Joint ADR Certification with Stipulation to ADR Process or Notice of Need for ADR Phone Conference	<u>FRCivP 26(f) & ADR L.R.3-5</u> <u>Civil L.R. 16-8</u>
5/14/2008	*Last day to file Rule 26(f) Report, complete initial disclosures or state objection in Rule 26(f) Report and file Case Management Statement per attached Standing Order re Contents of Joint Case Management Statement (also available at http://www.cand.uscourts.gov)	<u>FRCivP 26(a) (1)</u> <u>Civil L.R. 16-9</u>
5/21/2008	INITIAL CASE MANAGEMENT CONFERENCE (CMC) in Courtroom C,15th Floor,SF at 1:30 PM	<u>Civil L.R. 16-10</u>

* If the Initial Case Management Conference is continued, the other deadlines are continued accordingly.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

No.

Plaintiff(s),

v.

**CASE MANAGEMENT
CONFERENCE ORDER**

Defendant(s).

CASE MANAGEMENT CONFERENCE

IT IS HEREBY ORDERED that, pursuant to Federal Rules of Civil Procedure 16 and Civil Local Rules 16-10, a Case Management Conference will be held in this case before the Honorable Edward M. Chen on _____, at 1:30 p.m., in Courtroom C, 15th Floor, U.S. District Court, 450 Golden Gate Avenue, San Francisco, California. The parties are required to appear in court at 1:00 p.m., thirty (30) minutes prior to the Case Management Conference, to discuss the case with one another including disclosure of relevant information and any possibilities for settlement.

1. Plaintiff(s) shall serve copies of this Order and the Court's Standing Order for All Judges of the Northern District of California re: Contents of Joint Case Management Statement on all parties to this action, and on any parties subsequently joined, in accordance with the provisions of Fed. R. Civ. P. 4 and 5. Following service, Plaintiff(s) shall file a certificate of service with the Clerk of Court.

2. Lead trial counsel who will try this case are directed to confer in advance of the Case Management Conference with respect to the subjects detailed in Fed. R. Civ. P. 16©, 26(f), and all of

1 of the items referenced in the Court's Standing Order re: Contents of Joint Case Management
2 Statement. Not less than seven (7) days before the conference, counsel shall file a Joint Case
3 Management Conference Statement in compliance with Local Rule 16 and the Court's Standing
4 Order. All documents filed with the Clerk of Court shall list the civil case number followed only by
5 the initials "EMC." One copy shall be clearly marked as "EMC Chambers' Copy." Failure to file
6 a Joint Case Management Conference Statement, without good cause, may subject a party to
7 sanctions.

8 3. Each party shall be represented at the Case Management Conference by lead trial
9 counsel (or a party if *in pro se*) prepared to address all of the matters referred to in the Court's
10 Standing Order, and with authority to enter stipulations and make admissions pursuant to this Order.

11 4. Any request to reschedule the above dates should be made in writing, and by
12 stipulation, if possible, not less than ten (10) days before the conference date. Good cause must be
13 shown.

14 5. In all "E-Filing" cases, when filing papers that require the Court to take any
15 action (e.g. motions, meet and confer letters, administrative requests), the parties shall, in
16 addition to filing papers electronically, lodge with chambers a printed copy of the papers on
17 three-hole punch paper (including all exhibits) by the close of the next court day following the
18 day the papers are filed electronically. These printed copies shall be marked "EMC Chambers
19 Copy" and shall be submitted to the Clerk's Office in an envelope clearly marked with the case
20 number, "Magistrate Judge Edward M. Chen," and "E-Filing Chambers Copy." Parties shall
21 not file a paper copy of any document with the Clerk's Office that has already been filed
22 electronically. A proposed order in an E-Filing case must be emailed to
23 emcipo@cand.uscourts.gov as a Word Processing format attachment on the same day that it is
24 E-Filed. With permission, Chambers' copies of documents may be submitted on CD-ROM with
25 hypertext links to exhibits.

26 6. Each attorney of record in all "E-Filing" cases is obligated to become an ECF User
27
28

1 and be assigned a user ID and password for access to the system upon designation of the action as
2 being subject to ECF. Registration shall be on a form prescribed by the Clerk. Attorneys of record
3 who fail to register timely shall be subject to such sanctions as may be imposed by the Court.

4 7. Failure to comply with this Order, or provisions of the Fed. R. Civ. P. 16 and 26(f) or
5 the provisions of Civil L. R. 16-10 may be grounds for sanctions. (See Fed. R. Civ. P. 16(f)).

6 IT IS SO ORDERED.

7
8 Dated: March 1, 2007


EDWARD M. CHEN
United States Magistrate Judge

For the Northern District of California

**STANDING ORDER FOR ALL JUDGES OF THE NORTHERN DISTRICT OF
CALIFORNIA**

CONTENTS OF JOINT CASE MANAGEMENT STATEMENT

Commencing March 1, 2007, all judges of the Northern District of California will require the identical information in Joint Case Management Statements filed pursuant to Civil Local Rule 16-9. The parties must include the following information in their statement which, except in unusually complex cases, should not exceed ten pages:

1. Jurisdiction and Service: The basis for the court's subject matter jurisdiction over plaintiff's claims and defendant's counterclaims, whether any issues exist regarding personal jurisdiction or venue, whether any parties remain to be served, and, if any parties remain to be served, a proposed deadline for service.
2. Facts: A brief chronology of the facts and a statement of the principal factual issues in dispute.
3. Legal Issues: A brief statement, without extended legal argument, of the disputed points of law, including reference to specific statutes and decisions.
4. Motions: All prior and pending motions, their current status, and any anticipated motions.
5. Amendment of Pleadings: The extent to which parties, claims, or defenses are expected to be added or dismissed and a proposed deadline for amending the pleadings.
6. Evidence Preservation: Steps taken to preserve evidence relevant to the issues reasonably evident in this action, including interdiction of any document-destruction program and any ongoing erasures of e-mails, voice mails, and other electronically-recorded material.
7. Disclosures: Whether there has been full and timely compliance with the initial disclosure requirements of Fed. R. Civ. P. 26 and a description of the disclosures made.
8. Discovery: Discovery taken to date, if any, the scope of anticipated discovery, any proposed limitations or modifications of the discovery rules, and a proposed discovery plan pursuant to Fed. R. Civ. P. 26(f).
9. Class Actions: If a class action, a proposal for how and when the class will be certified.
10. Related Cases: Any related cases or proceedings pending before another judge of this court, or before another court or administrative body.
11. Relief: All relief sought through complaint or counterclaim, including the amount of any

damages sought and a description of the bases on which damages are calculated. In addition, any party from whom damages are sought must describe the bases on which it contends damages should be calculated if liability is established.

12. Settlement and ADR: Prospects for settlement, ADR efforts to date, and a specific ADR plan for the case, including compliance with ADR L.R. 3-5 and a description of key discovery or motions necessary to position the parties to negotiate a resolution.

13. Consent to Magistrate Judge For All Purposes: Whether all parties will consent to have a magistrate judge conduct all further proceedings including trial and entry of judgment.

14. Other References: Whether the case is suitable for reference to binding arbitration, a special master, or the Judicial Panel on Multidistrict Litigation.

15. Narrowing of Issues: Issues that can be narrowed by agreement or by motion, suggestions to expedite the presentation of evidence at trial (e.g., through summaries or stipulated facts), and any request to bifurcate issues, claims, or defenses.

16. Expedited Schedule: Whether this is the type of case that can be handled on an expedited basis with streamlined procedures.

17. Scheduling: Proposed dates for designation of experts, discovery cutoff, hearing of dispositive motions, pretrial conference and trial.

18. Trial: Whether the case will be tried to a jury or to the court and the expected length of the trial.

19. Disclosure of Non-party Interested Entities or Persons: Whether each party has filed the "Certification of Interested Entities or Persons" required by Civil Local Rule 3-16. In addition, each party must restate in the case management statement the contents of its certification by identifying any persons, firms, partnerships, corporations (including parent corporations) or other entities known by the party to have either: (i) a financial interest in the subject matter in controversy or in a party to the proceeding; or (ii) any other kind of interest that could be substantially affected by the outcome of the proceeding.

20. Such other matters as may facilitate the just, speedy and inexpensive disposition of this matter.

Lawrence J. Gornick (SBN 136290)
Debra DeCarli (SBN 237642)
LEVIN SIMES KAISER & GORNICK LLP
44 Montgomery Street, 36th Floor
San Francisco, CA 94104
Telephone: (415) 646-7160
Fax: (415) 981-1270
lgornick@lskg-law.com
ddecarli@lskg-law.com

Attorneys for Plaintiffs

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION**

JOE V. SANCHEZ and SANDRA L.
ROARTY-SANCHEZ,

Plaintiffs,

vs.

BAYER HEALTHCARE
PHARMACEUTICALS, INC.; BAYER
HEALTHCARE LLC; GENERAL ELECTRIC
COMPANY; GE HEALTHCARE, INC.;
TYCO INTERNATIONAL, INC.; COVIDIEN,
INC.; TYCO HEALTHCARE GROUP, LP;
MALLINCKRODT, INC.; BRACCO
DIAGNOSTICS, INC.; McKESSON
CORPORATION; MERRY X-RAY
CHEMICAL CORP.; and DOES 1 through 35

Defendants.

Case No: CV -08-0973-EMC

**PROOF OF SERVICE VIA US MAIL OF
SUMMONS, CIVIL COVER SHEET,
ORIGINAL COMPLAINT – DEMAND FOR
JURY TRIAL, ORDER SETTING INITIAL
CASE MANAGEMENT CONFERENCE
AND ADR DEADLINES, U.S. DISTRICT
COURT NORTHERN CALIFORNIA ECF
REGISTRATION INFORMATION
HANDOUT, and NOTICE OF ASSIGNMENT
OF CASE TO A UNITED STATES
MAGISTRATE JUDGE FOR TRIAL**

I certify that I am over the age of 18 years and not a party to the within action; that my business address is 44 Montgomery Street, 36th Floor, San Francisco, CA 94104; and that on this date I served a true copy of the document(s) entitled:

Service was effectuated by forwarding the above-noted document in the following manner:

XX By Regular Mail in a sealed envelope, addressed as noted above, with postage fully prepaid and placing it for collection and mailing following the ordinary business practices of Levin Simes Kaiser & Gornick.

By Electronic Mail

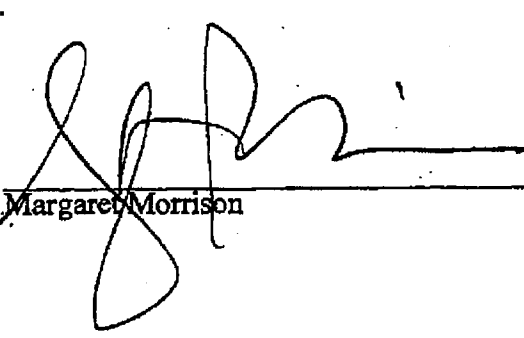
By Hand Delivery in a sealed envelope, addressed as noted above, through services provided by the office of Levin Simes Kaiser & Gornick.

1 By **Facsimile** to the numbers as noted below by placing it for facsimile transmittal following
 2 the ordinary business practices of Levin Simes Kaiser & Gornick.

3 By **Overnight Courier** in a sealed envelope, addressed as noted above, through services
 4 provided by (Federal Express, UPS,) and billed to Levin Simes Kaiser & Gornick.

5 Bayer Healthcare Pharmaceuticals Inc. c/o CSC-Lawyers Incorporating Service 2730 Gateway Oaks Drive, Suite 100 6 Sacramento CA 94883	Bayer Healthcare LLC c/o CSC-Lawyers Incorporating Service 2730 Gateway Oaks Drive, Suite 100 Sacramento CA 94883
7 General Electric Company 8 c/o CT Corporation System 818 West Seventh Street 9 Los Angeles CA 90017	GE Healthcare Inc. c/o CT Corporation System 818 West Seventh Street Los Angeles CA 90017
10 Tyco International Inc. 11 c/o CT Corporation System 818 West Seventh Street 12 Los Angeles CA 90017	Covidien Inc. c/o CT Corporation System 818 West Seventh Street Los Angeles CA 90017
13 Tyco Healthcare Group LP 14 c/o CT Corporation System 818 West Seventh Street 15 Los Angeles CA 90017	Mallinckrodt Inc. c/o CT Corporation System 818 West Seventh Street Los Angeles CA 90017
16 Bracco Diagnostics Inc. 17 c/o CT Corporation System 818 West Seventh Street 18 Los Angeles CA 90017	

19 I declare under penalty of perjury that the foregoing is true and correct. Executed this 19th day
 20 of January 2008 at San Francisco, California.
 21

22 
 23
 24 Margaret Morrison
 25
 26
 27
 28

FROM: Mara Velasco (213)337-4616
CT - Los Angeles SOP Team
818 West Seventh Street

Los Angeles, CA 90017

TO: **Michael Von Ohlen (609)514-2303**
Bracco Diagnostics, Inc.
107 College Road East



FedEx Revenue Barcode

CAD#: 8318649
SHIP DATE: 11MAR08
WEIGHT: 1 LB

Princeton, NJ 08540

Ref: SOP/0413900/513180276/Mara Velasco



DELIVERY ADDRESS (FedEx-EDR)

STANDARD OVERNIGHT

TRK # 7910 1878 0631

FORM
0201

EWR

08540 -NJ-US

07 PRIA



WED
A2

Deliver by:
12MAR08

CLS120707

EXHIBIT “E”

E-67

FILED
U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO
MAY 20 2008
CLERK OF COURT

Lawrence J. Gornick (SBN 136290)
Debra DeCarli (SBN 237642)
LEVIN SIMES KAISER & GORNICK LLP
44 Montgomery Street, 36th Floor
San Francisco, CA 94104
Telephone: (415) 646-7160
Fax: (415) 981-1270
lgornick@lskg-law.com
ddecarli@lskg-law.com

Attorneys for Plaintiffs

E-filing

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION**

ORELLENE SEABOLD,

Plaintiff,

Case No:

vs.

**BAYER HEALTHCARE
PHARMACEUTICALS, INC.; BAYER
HEALTHCARE LLC; GENERAL ELECTRIC
COMPANY; GE HEALTHCARE, INC.;
COVIDIEN, INC.; MALLINCKRODT, INC.;
and BRACCO DIAGNOSTICS, INC.**

ORIGINAL COMPLAINT

EMC

DEMAND FOR JURY TRIAL

Defendants.

Plaintiff, Orellene Seabold, (hereinafter "Plaintiff") alleges as follows:

NATURE OF THE CASE

1. Plaintiff Orellene Seabold ("Ms. Seabold" or "Plaintiff") has nephrogenic systemic fibrosis ("NSF"). NSF is an incurable, painful, and deadly disease. Ms. Seabold contracted NSF as a result of receiving intravenous injections of gadolinium-based contrast agents manufactured by the Defendants. Gadolinium-based contrast agents are not safe for use in individuals such as Plaintiff who have impaired kidney function. Defendants represented that the gadolinium-based contrast agents were safe and failed to warn of the risks associated with gadolinium-based contrast agents.

JURISDICTION AND VENUE

2. This Court has jurisdiction pursuant to 28 USC § 1332. Plaintiff is a citizen of a state that is different from the states where Defendants are incorporated and have their respective principal places of business. The amount in controversy for this case exceeds \$75,000. Venue pursuant to

1 28 USC § 1391(c) is proper because Defendants have sufficient contacts within the City and County of
2 San Francisco, California to subject each of them to personal jurisdiction.

3 **INTRADISTRICT ASSIGNMENT**

4 3. On information and belief, a substantial part of the events or omissions which give rise
5 to the claim occurred in the City and County of San Francisco.

6 **PARTIES**

7 ***Plaintiff***

8 4. Orellene Seabold is a resident of the State of Tennessee.

9 ***Defendants***

10 5. Defendants Bayer HealthCare Pharmaceuticals, Inc. and Bayer Healthcare LLC (jointly
11 referred to as "Bayer") manufacture, market, and sell Magnevist, a gadolinium-based contrast agent
12 that, on information and belief, was injected into Plaintiff.

13 6. Defendant Bayer HealthCare LLC is a Delaware business entity with its principal place
14 of business in New York.

15 7. Defendant Bayer HealthCare Pharmaceuticals, Inc. is a Delaware business entity with
16 its principal place of business in New Jersey. Defendant Bayer HealthCare Pharmaceuticals, Inc. is
17 the U.S.-based pharmaceuticals unit of Bayer Healthcare LLC.

18 8. At all times relevant to this complaint, Bayer was in the business of designing,
19 licensing, manufacturing, distributing, selling, marketing, promoting, and introducing Magnevist into
20 interstate commerce.

21 9. Defendants General Electric Company and GE Healthcare, Inc. (jointly referred to as
22 "GE") manufacture, market, and sell Omniscan, a gadolinium-based contrast agent that, on
23 information and belief, was injected into Plaintiff.

24 10. Defendant General Electric Company is a New York business entity with its principal
25 place of business in Connecticut.

26 11. Defendant GE Healthcare, Inc. is a Delaware corporation with its principal place of
27 business in New Jersey.

28 12. At all times relevant to this complaint, GE was in the business of designing, licensing,

1 manufacturing, distributing, selling, marketing, promoting, and introducing Omniscan into interstate
2 commerce.

3 13. Defendants Covidien Inc. and Mallinckrodt, Inc. (collectively referred to as
4 "Covidien") manufacture, market, and sell OptiMARK, a gadolinium-based contrast agent that, on
5 information and belief, was injected into Plaintiff.

6 14. Defendant Covidien, Inc. is a Delaware corporation with its principal place of business
7 in New Hampshire.

8 15. Defendant Mallinckrodt, Inc. is a Delaware corporation with its principal place of
9 business in Missouri. Mallinckrodt is a business unit of Covidien, Inc.

10 16. At all times relevant to this complaint, Covidien was in the business of designing,
11 licensing, manufacturing, distributing, selling, marketing, promoting, and introducing OptiMARK into
12 interstate commerce.

13 17. Defendant Bracco Diagnostics, Inc. ("Bracco") manufactures, markets, and sells
14 MultiHance and ProHance, gadolinium-based contrast agents that, on information and belief, were
15 injected into Plaintiff.

16 18. Bracco Diagnostics, Inc. is a Delaware corporation with its principal place of business
17 in New Jersey.

18 19. At all times relevant to this complaint, Bracco was in the business of designing,
19 licensing, manufacturing, distributing, selling, marketing, promoting, and introducing MultiHance and
20 ProHance into interstate commerce.

21 20. The Bayer, GE, Covidien, and Bracco Defendants are collectively referred to as
22 Defendants.

23 **FACTS**

24 21. Ms. Seabold was diagnosed with NSF in or around September of 2007.

25 22. NSF is predominantly characterized by discoloration, thickening, tightening, and
26 swelling of the skin after receiving a gadolinium-based contrast agent injection. These fibrotic and
27 edematous changes produce muscular weakness and inhibit flexion and extension of joints, resulting in
28 contractures. NSF often progresses to painful inhibition of the ability to use the arms, legs, hands,

1 feet, and other joints. The skin changes that begin as darkened patches or plaques progress to a
2 "woody" texture and are accompanied by burning, itching, or severe pain in the areas of involvement.
3 NSF also progresses to a fibrotic or scarring condition of other body organs such as the lungs, heart,
4 liver, and musculature, and that can inhibit their ability to function properly and may lead to death.
5 NSF is a progressive disease for which there is no known cure.

6 23. NSF is a man-made disease. It only occurs in patients who have received a gadolinium-
7 based contrast agent.

8 24. Gadolinium is a highly toxic heavy metal. It does not occur naturally in the human
9 body. The only known route for gadolinium to enter the human body is injection of a gadolinium-
10 based contrast agent.

11 25. Because gadolinium is toxic, it has to be coated to keep it from coming in contact with
12 human tissue when injected. This coating process is called chelation.

13 26. Gadolinium is eliminated from the body by the kidneys. Gadolinium-based contrast
14 agents are not safe if the chelate separates from the gadolinium, which is what happens over time if
15 kidneys are not functioning properly. Individuals with impaired kidney function risk dechelation, and
16 cannot efficiently or quickly eliminate gadolinium from their bodies. Defendants never tested the
17 safety of their gadolinium-based contrast agents in individuals with kidney impairment.

18 27. On information and belief, the gadolinium-based contrast agents injected into Plaintiff
19 were manufactured by Defendants.

20 28. In pre-clinical studies during which gadolinium-based contrast agents were injected into
21 laboratory animals, consistent patterns of toxicity including nephrogenic fibrotic changes in the
22 kidneys and other body organs occurred.

23 29. During the years that Defendants have manufactured, marketed, distributed, sold, and
24 administered gadolinium-based contrast agents, there have been numerous case reports, studies,
25 assessments, papers, and other clinical data that have described and/or demonstrated NSF in
26 connection with the use of gadolinium-based contrast agents.

27 30. Plaintiff received MRIs and/or MRAs utilizing gadolinium-based contrast agents.

28 31. Plaintiff had impaired kidney function at the time she received her first injection of

1 gadolinium-based contrast agent and continued to have impaired kidney function at the time she
2 received each subsequent injection of gadolinium-based contrast agent.

3 32. During the time period when Plaintiff received injections of Defendants' gadolinium-
4 based contrast agents, Defendants knew or should have known that the use of gadolinium-based
5 contrast agents created a risk of serious bodily injury and death in patients with impaired kidney
6 function.

7 33. Defendants failed to warn Plaintiff and her healthcare providers about the serious health
8 risks associated with gadolinium-based contrast agents, and failed to disclose the fact that there were
9 safer alternatives.

10 34. As a direct and proximate result of receiving injections of gadolinium-based contrast
11 agents manufactured, marketed, distributed, and sold by Defendants, Plaintiff developed NSF.

12 35. Defendants have repeatedly and consistently failed to advise consumers and/or their
13 healthcare providers of the causal relationship between gadolinium-based contrast agents and NSF in
14 patients with kidney impairment. Defendants knew or should have known of the risk of NSF posed by
15 gadolinium-based contrast agents to individuals with impaired kidney function years before they
16 finally issued warnings.

17 36. It was not until September 2007 that Bayer, GE, Bracco, and Mallinckrodt finally sent
18 letters to healthcare providers warning them of the risk of NSF to kidney impaired individuals who
19 received MRIs using gadolinium-based contrast agents.

20 37. Had Plaintiff and/or her healthcare providers been warned about the risks associated
21 with gadolinium-based contrast agents, she would not have been administered gadolinium-based
22 contrast agents and would not have been afflicted with NSF.

23 38. As a direct and proximate result of Plaintiff being administered gadolinium-based
24 contrast agents, she has suffered severe physical injury and pain and suffering, including, but not
25 limited to, the effects of NSF. Plaintiff's physical injuries and pain and suffering will inevitably
26 worsen over time and will in all likelihood lead to death.

27 39. As a direct and proximate result of being administered gadolinium-based contrast
28 agents, Plaintiff suffered and continues to suffer significant mental anguish and emotional distress and

1 will continue to suffer significant mental anguish and emotional distress in the future.

2 40. As a direct and proximate result of being administered gadolinium-based contrast
3 agents, Plaintiff has also incurred medical expenses and other economic damages and will continue to
4 incur such expenses in the future.

5 **DISCOVERY RULE & FRAUDULENT CONCEALMENT**

6 41. The discovery rule should be applied to toll the running of the statute of limitations
7 until Plaintiff knew or through the exercise of reasonable care and diligence should have known of the
8 existence of her claims against all Defendants. The nature of Plaintiff's injuries and damages, and
9 their relationship to gadolinium-based contrast agents used in conjunction with MRIs and MRAs, was
10 not discovered, and through reasonable care and due diligence could not have been discovered, by
11 Plaintiff, until a time less than two years before the filing of this Complaint. Therefore, under
12 appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable
13 statutory limitations period.

14 42. Defendants are estopped from asserting a statute of limitations defense because all
15 Defendants fraudulently concealed from Plaintiff the nature of Plaintiff's injury and the connection
16 between the injury and all Defendants' tortious conduct.

17 **FIRST CAUSE OF ACTION**

18 **STRICT LIABILITY: FAILURE TO WARN**

19 43. Plaintiff incorporates by reference and realleges each paragraph set forth above.

20 44. Defendants' gadolinium-based contrast agents, and MRI and MRA machines designed
21 to be used in conjunction with gadolinium-based contrast agents, were defective due to inadequate
22 warnings or instruction for use, both prior to marketing and post-marketing. Defendants knew or
23 should have known that their products created significant risks of serious bodily harm and death to
24 consumers. Defendants failed to adequately warn consumers and their healthcare providers of such
25 risks.

26 45. Because of Defendants' failure to provide adequate warnings with their products,
27 Plaintiff was injected with gadolinium-based contrast agents that the Defendants manufactured,
28 designed, sold, supplied, marketed, or otherwise introduced into the stream of commerce. Those

1 gadolinium-based contrast agents are the legal cause of Plaintiff's physical injuries, harm, damages,
2 and economic loss. Plaintiff will continue to suffer such harm, damages, and economic loss in the
3 future.

4 **SECOND CAUSE OF ACTION**

5 **STRICT LIABILITY: DESIGN DEFECT**

6 46. Plaintiff incorporates by reference and realleges each paragraph set forth above.

7 47. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of
8 gadolinium-based contrast agents, and MRI and MRA machines designed to be used in conjunction
9 with gadolinium-based contrast agents.

10 48. The gadolinium-based contrast agents manufactured and supplied by Defendants were
11 defective in design or formulation in that, when they left the hands of the Defendants, the foreseeable
12 risks of the products exceeded the benefits associated with their design or formulation; or were more
13 dangerous than an ordinary consumer would expect.

14 49. The foreseeable risks associated with the design or formulation of gadolinium-based
15 contrast agents, and MRI and MRA machines designed to be used in conjunction with gadolinium-
16 based contrast agents, include, but are not limited to, the fact that the design or formulation of
17 gadolinium-based contrast agents are more dangerous than a reasonably prudent consumer would
18 expect when used in an intended or reasonably foreseeable manner.

19 50. As a direct and proximate result of Plaintiff being administered gadolinium-based
20 contrast agents as manufactured, designed, sold, supplied, marketed, and introduced into the stream of
21 commerce by Defendants, Plaintiff has suffered physical injury, harm, damages, and economic loss
22 and will continue to suffer such harm, damages, and economic loss in the future.

23 **THIRD CAUSE OF ACTION**

24 **STRICT LIABILITY: FAILURE TO ADEQUATELY TEST**

25 51. Plaintiff incorporates by reference and realleges each paragraph set forth above.

26 52. Defendants advised consumers and the medical community that gadolinium-based
27 contrast agents were safe for use. Defendants failed to adequately test gadolinium-based contrast
28 agents with respect to their use by consumers with kidney impairment.

1 53. Had Defendants adequately tested the safety of gadolinium-based contrast agents for
2 use by consumers with kidney impairment and disclosed those results to the medical community or the
3 public, Plaintiff would not have been administered gadolinium-based contrast agents.

4 54. As a direct and proximate result of Defendants' failure to adequately test the safety of
5 gadolinium-based contrast agents and as a direct and proximate result of Plaintiff being administered
6 gadolinium-based contrast agents as manufactured, designed, sold, supplied, marketed, and introduced
7 into the stream of commerce by Defendants, Plaintiff has suffered physical injury, harm, damages, and
8 economic loss and will continue to suffer such harm, damages, and economic loss in the future.

9 **FOURTH CAUSE OF ACTION**

10 **NEGLIGENCE**

11 55. Plaintiff incorporates by reference and realleges each paragraph set forth above.

12 56. Defendants had a duty to exercise reasonable care in the design, formulation, testing,
13 manufacture, labeling, marketing, sale and/or distribution of gadolinium-based contrast agents and the
14 MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents.
15 In particular, they had a duty to assure that their products did not pose an unreasonable risk of bodily
16 harm and adverse events.

17 57. Defendants failed to exercise reasonable care in the design, formulation, manufacture,
18 sale, testing, marketing, or distribution of gadolinium-based contrast agents and the MRI and MRA
19 machines designed to be used in conjunction with gadolinium-based contrast agents in that they knew
20 or should have known that the products could cause significant bodily harm or death and were not safe
21 for use by certain types of consumers.

22 58. Defendants failed to exercise ordinary care in the labeling of gadolinium-based contrast
23 agents and the labeling of MRI and MRA machines designed to be used in conjunction with
24 gadolinium-based contrast agents and failed to issue to consumers and their health care providers
25 adequate warnings concerning the risks of serious bodily injury or death due to the use of gadolinium-
26 based contrast agents and the MRI and MRA machines designed to be used in conjunction with
27 gadolinium-based contrast agents.

28 59. Despite the fact that Defendants knew or should have known that gadolinium-based

1 contrast agents and the MRI and MRA machines designed to be used in conjunction with gadolinium-
 2 based contrast agents posed a serious risk of bodily harm to consumers, Defendants unreasonably
 3 continued to manufacture and market gadolinium-based contrast agents and the MRI and MRA
 4 machines designed to be used in conjunction with gadolinium-based contrast agents for administration
 5 to MRI and MRA patients with kidney impairment and failed to exercise reasonable care with respect
 6 to post-sale warnings and instructions for safe use.

7 60. At all relevant times, it was foreseeable to Defendants that consumers like Plaintiff
 8 would suffer injury as a result of their failure to exercise ordinary care as described above.

9 61. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered
 10 physical injuries, harm, damages, and economic loss and will continue to suffer such harm, damages
 11 and economic loss in the future.

12 62. The foregoing acts, conduct and omissions of Defendants were vile, base, willful,
 13 malicious, wanton, oppressive, and fraudulent, and were done with a conscious disregard for the
 14 health, safety, and rights of Plaintiff and other users of Defendants' products, and for the primary
 15 purpose of increasing Defendants' profits. As such, Plaintiff is entitled to exemplary damages.

16 **FIFTH CAUSE OF ACTION**

17 **NEGLIGENT MISREPRESENTATION**

18 63. Plaintiff incorporates by reference and realleges each paragraph set forth above.

19 64. Defendants supplied the public and Plaintiff's healthcare providers with materially false
 20 and incomplete information with respect to the safety of their gadolinium-based contrast agents.

21 65. The false information supplied by Defendants was that gadolinium-based contrast
 22 agents were safe.

23 66. In supplying this false information, Defendants failed to exercise reasonable care.

24 67. The false information communicated by Defendants to Plaintiff and her healthcare
 25 providers was material and Plaintiff justifiably relied in good faith on the information to her detriment.

26 68. As a direct and proximate result of Defendants' misrepresentations, Plaintiff was
 27 administered gadolinium-based contrast agents and has suffered physical injury, harm, damages, and
 28 economic loss and will continue to suffer such harm, damages, and economic loss in the future.

SIXTH CAUSE OF ACTION

FRAUD

69. Plaintiff incorporates by reference and realleges each paragraph set forth above.

70. Defendants knowingly and intentionally made materially false and misleading representations to Plaintiff's healthcare providers and to the public, to the effect that gadolinium-based contrast agents were safe for use and that their labeling, marketing, and promotional materials fully described all known risks associated with their product.

71. Defendants' representations were in fact false. Gadolinium-based contrast agents are not safe for use and Defendants' labeling, marketing, and promotional materials did not fully describe all known risks of the products.

72. Defendants had actual knowledge that gadolinium-based contrast agents created an unreasonable risk of serious bodily injury and death to consumers, especially patients with kidney impairment.

73. Defendants knowingly and intentionally omitted this information from their labeling, marketing, and promotional materials and instead, labeled, promoted, and marketed their products as safe for use in order to increase and sustain sales.

74. When Defendants made representations that gadolinium-based contrast agents were safe for use, they knowingly and intentionally concealed and withheld from Plaintiff, her healthcare providers, and the public, the fact that their gadolinium-based contrast agents are not safe for use in consumers with kidney impairment.

75. Defendants had a duty to disclose that gadolinium-based contrast agents are not safe for use in patients with kidney impairment. Defendants had superior knowledge of these facts that were material to Plaintiff and her healthcare providers' decisions to use gadolinium-based contrast agents.

76. Plaintiff and her healthcare providers reasonably and justifiably relied on the Defendants' representations that gadolinium-based contrast agents were safe for human use and that Defendants' labeling, marketing, and promotional materials fully described all known risks associated with the products.

77. Plaintiff did not know and could not have learned of the facts that the Defendants

omitted and suppressed. The facts suppressed and concealed by the Defendants are material. Had Plaintiff and her healthcare providers known that gadolinium-based contrast agents are not safe for use in patients with renal insufficiency, Plaintiff would not have been injected with gadolinium-based contrast agents.

78. As a direct and proximate result of Defendants' misrepresentations and concealment, Plaintiff was administered gadolinium-based contrast agents and has suffered physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

79. The foregoing acts, conduct, and omissions of Defendants were vile, base, willful, malicious, wanton, oppressive, and fraudulent, and were done with a conscious disregard for the health, safety, and rights of Plaintiff and other users of Defendants' products, and for the primary purpose of increasing Defendants' profits. As such Plaintiff is entitled to exemplary damages.

SEVENTH CAUSE OF ACTION

FRAUD: CONCEALMENT, SUPPRESSION OR OMISSION OF MATERIAL FACTS

80. Plaintiff incorporates by reference and realleges each paragraph set forth above.

81. Defendants omitted, suppressed, or concealed material facts concerning the dangers and risk associated with the use of their gadolinium-based contrast agents, including but not limited to the risks to patients with kidney impairment of developing NSF, and the fact that safer alternatives were available. Further, Defendants purposely downplayed and understated the serious nature of the risks associated with use of their gadolinium-based contrast agents in order to increase and sustain sales.

82. As a direct and proximate result of Defendants' concealment of material facts, Plaintiff was administered gadolinium-based contrast agents and has suffered physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

83. The foregoing acts, conduct, and omissions of Defendants were vile, base, willful, malicious, wanton, oppressive, and fraudulent, and were done with a conscious disregard for the health, safety, and rights of Plaintiff and other users of Defendants' products, and for the primary purpose of increasing Defendants' profits. As such Plaintiff is entitled to exemplary damages.

EIGHTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

84. Plaintiff incorporates by reference and realleges each paragraph set forth above.

85. Defendants expressly warranted that gadolinium-based contrast agents were safe and effective.

86. The gadolinium-based contrast agents manufactured and sold by Defendants did not conform to these express representations because they cause serious injury to consumers when administered in recommended dosages.

87. As a direct and proximate result of Defendants' breach of warranty, Plaintiff has suffered physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

NINTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

88. Plaintiff incorporates by reference and realleges each paragraph set forth above.

89. At the time Defendants designed, manufactured, marketed, sold, and distributed gadolinium-based contrast agents, Defendants knew of the use for which gadolinium-based contrast agents was intended and impliedly warranted the product to be of merchantable quality and safe for such use.

90. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether gadolinium-based contrast agents were of merchantable quality and safe for their intended use and upon Defendants' implied warranty as to such matters.

91. Contrary to such implied warranty, gadolinium-based contrast agents were not of merchantable quality or safe for their intended use because the product was unreasonably dangerous as described above.

92. As a direct and proximate result of Defendants' breach of warranty, Plaintiff has suffered physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

//// //

TENTH CAUSE OF ACTION

VIOLATION OF TENNESSEE CONSUMER PROTECTION STATUTES

93. Plaintiff incorporates by reference and realleges each paragraph set forth above.

94. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code Ann. § 47-18-109(a)(1) *et seq.* including but not limited to the following:

a. Marketing, promoting or selling Magnevist, Omniscan, OptiMark, MultiHance, or ProHance for use with MRAs and other off-label uses by impliedly representing that such products are approved for use with MRAs and other off-label uses, when in fact there is no such approval;

b. Representing that gadolinium-based contrast agents are safe and effective for all patients, including patients with kidney impairment, when in fact they are not;

c. Representing that MRIs and MRAs using gadolinium-based contrast agents are safer or more effective than other imaging methods that do not require the use of gadolinium-based contrast agents when in fact they are not;

d. Marketing, promoting, or selling their products as safer or superior to other brands of gadolinium-based contrast agents;

e. Marketing, promoting, or selling Magnevist, Omniscan, OptiMark, MultiHance, or ProHance as inert or with words to that effect;

f. Marketing, promoting, or selling Magnevist, Omniscan, OptiMark, MultiHance, or ProHance for use with MRAs or other off-label uses by expressly or impliedly representing that they are safe for such use; and

g. Remaining silent despite their knowledge of the growing body of evidence regarding the danger of NSF and doing so because the prospect of huge profits outweighed health and safety issues.

95. As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive actions or practices, Plaintiff was administered gadolinium-based contrast agents and has suffered serious physician injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

WHEREFORE, Plaintiff prays for relief as follows:

1. Compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, loss of consortium, and other non-economic damages in an amount to be determined at trial of this action;
2. Past and future medical expenses, income, and other economic damages in an amount to be determined at trial of this action;
3. Punitive damages in an amount to be determined at trial of this action;
4. Pre- and post-judgment interest;
5. Attorneys' fees, expenses, and costs; and
6. Such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury.

Respectfully submitted this 7th day of March, 2008.

LEVIN SIMES KAISER & GORNICK LLP

By: Debra DeCarli

Debra DeCarli, Esq.

TUCKER ELLIS & WEST LLP
MICHAEL C. ZELLERS-STATE BAR NO. 146904
MOLLIE BENEDICT-STATE BAR NO. 187084
AGGIE B. LEE-STATE BAR NO. 228332
515 S. Flower Street, 42nd Floor
Los Angeles, CA 90071-2223
Telephone: (213) 430-3400
Facsimile: (213) 430-3409
michael.zellers@tuckerellis.com
mollie.benedict@tuckerellis.com
aggie.lee@tuckerellis.com

Attorneys for Defendant
BRACCO DIAGNOSTICS INC.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

CAROL MOORHOUSE and JAMES
MOORHOUSE,

Plaintiffs,

v.

BAYER HEALTHCARE
PHARMACEUTICALS, INC.; BAYER
HEALTHCARE LLC; GENERAL
ELECTRIC COMPANY; GE
HEALTHCARE, INC.; COVIDIEN,
INC.; MALLINCKRODT, INC.;
BRACCO DIAGNOSTICS, INC.;
McKESSON CORPORATION;
MERRY X-RAY CHEMICAL CORP.;
and DOES 1 through 35,

Defendants.

Case No. CV-08-1831 SBA

**[PROPOSED] ORDER DENYING
PLAINTIFFS' MOTION TO
REMAND**

[Filed Concurrently with BDI's
Opposition to Motion to Remand and
Declaration of Aggie B. Lee]

Date: June 10, 2008
Time: 1:00 p.m.
Courtroom: 3

[PROPOSED] ORDER

Plaintiffs' Motion to Remand and Defendants General Electric Company and GE Healthcare Inc.'s Application to Stay All Proceedings Pending MDL came on regularly for hearing before this Court on June 10, 2008.

After considering the papers filed, the arguments of counsel and all other matters presented to the Court, IT IS HEREBY ORDERED THAT Plaintiffs' Motion to Remand is DENIED.

IT IS FURTHER ORDERED THAT all further proceedings are stayed pending transfer to the designated Multidistrict Litigation Court—the United States District Court for the Northern District of Ohio, for inclusion in MDL 1909: *In re Gadolinium Contrast Dyes Product Liability Litigation*.

DATED: _____, 2008

The Honorable Sandra Brown Armstrong
United States District Court Judge